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Senate Hearing

Before the Committee on Appropriations

Childhood Immunization Program

Fiscal Year 1989

100th CONGRESS, SECOND SESSION

SPECIAL HEARING

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CHILDHOOD IMMUNIZATION PROGRAM

HEARING

BEFORE A

SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

SECOND SESSION

SPECIAL HEARING

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CONTENTS

Page

Opening statement of Hon. Dale Bumpers, U.S. Senator from Arkansas 1
Statement of Senator Dale Bumpers 5
Statement of Senator Lowell P. Weicker 10
Remarks by Senator Chiles 10
Statement of Hon. Henry A. Waxman, U.S. Representative from California 11
  Prepared statement 14
Statement of Dr. James Mason, Director, Centers for Disease Control, Department of Health and Human Services 18
  Prepared statement 21
Statement of Robert B. Johnson, president, Lederle Laboratories, American Cyanamid Co 40
  Prepared statement 43
Statement of Gerri Cohn, Dissatisfied Parents Together 52
Statement of Dr. Richard M. Narkewicz, president, American Academy of Pediatrics 52
Statement of Dr. Roberta Coffin, commissioner, Vermont Department of Health 52
Statement of Kay Johnson, senior health specialist, Children's Defense Fund 52
Prepared statement of Gerrie Cohn 54
Statement of Kay Johnson 55
  Prepared statement 59
Statement of Dr. Roberta Coffin 86
  Prepared statement 89
Letter from D.J. MacMaster, Jr., president, Merck Sharp & Dohme 93
Statement of Dr. Richard M. Narkewicz 95
  Prepared statement 99
Prepared statement of David J. Williams, president, Connaught Laboratories, Inc 113

CHILDHOOD IMMUNIZATION PROGRAM

TUESDAY, MARCH 15, 1988

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, EDUCATION AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 2:10 p.m., in room SR-428A, Russell Senate Office Building, Hon. Dale Bumpers presiding.

Present: Senators Chiles, Bumpers, and Weicker.

NONDEPARTMENTAL WITNESSES

OPENING STATEMENT OF HON. DALE BUMPERS, U.S. SENATOR FROM ARKANSAS

Senator BUMPERS. The committee will come to order.

First, I want to apologize to Chairman Waxman, and all the rest of you for being late. I would like to open this hearing with a statement about why we are here and what we hope to accomplish.

We are here to evaluate and consider suggestions for improvement of one of the most successful and cost effective preventive health programs in the country, the Childhood Immunization Program.

I have always considered this program to be the best example of a good public health program, one that prevents human disease and human suffering and also saves families, State governments, and the Federal Government a great deal of money.

The experience with the measles, mumps, rubella vaccine demonstrates the success of the immunization program. Since 1963, over 65 million cases of measles and 21,500 cases of mental retardation have been averted and 6,500 children's lives have been saved as a result of measles immunization. And in the 20 years since the measles vaccine's licensure in 1963, it has saved the United States $5.1 billion in direct and indirect costs.

The immunization program has been so successful that Americans take its success for granted. Young pediatricians have little knowledge of childhood diseases, like whooping cough, diphtheria, and polio because they have seen few or no cases.

And most Americans do not remember that as recently as 1962—we had 480,000 cases of measles reported and probably 10 times more actual cases. Many never knew about or have forgotten the 1952 polio epidemic. 21,000 cases of paralytic polio were reported in that year.

And few remember that in the 1930's there were 5,000 deaths annually from whooping cough.

A cursory look at the immunization program might lead to the conclusion that all is well in the program. For example, the immunization level for the 3.8 million children entering school in 1986 was 97 percent, a record high. And the Surgeon General's 1990 objectives for reported incidents of rubella, diphtheria, tetanus, and polio have already been achieved.

But a closer look at the program reveals some troubling trends: continued increases in vaccine prices, which in turn cause shortfalls in Federal and State immunization funding; stagnation or decline in immunization levels for preschool children; and an inability to guarantee American children access to recently developed vaccines which protect against childhood diseases.

Since 1982, we have seen the prices of vaccines skyrocket. In 1982, a DPT shot cost 37 cents in the private sector. In 1988, 6 short years later, the same vaccine will cost $11.03, a staggering 3,000-percent increase.

In 1982, a dose of the measles, mumps, rubella vaccine cost $10.44, and in 1988 we estimate that the same vaccine will cost $27.23.

Federal funding has increased from $30.4 million in fiscal year 1981 to more than $98 million in 1988. Yet increases in Federal funding, supplemented by increases in State funding, never seem to match manufacturers' price increases.

Unfortunately, the childhood vaccines cause injuries to a very small number of children who take them. The pertussis part of the DIP vaccine is blamed for the vast majority of vaccine-related injuries.

While most adverse reactions are mild, permanent neurological damage is caused by 1 in 310,000 doses of pertussis vaccine. Certainly those children who are injured by vaccines should be fairly compensated for the medical expenses, lost earnings, pain and suffering associated with the injury, and vaccine research must continue in our effort to provide the safest possible pertussis vaccine.

While we must do everything possible to improve the safety of the childhood vaccines, we cannot dismiss the benefits of the current vaccines. In the early 1930's, there were approximately 200,000 cases of whooping cough and 5,000 deaths annually. Provisional data indicates that there were only 2,529 cases of whooping cough in 1987.

During the 1980's, there has been a rapid increase in the number of injury suits filed against the manufacturers of childhood vaccines. Vaccine manufacturers told us through the 1980's that price increases could be directly attributed to the increased cost of liability insurance, when it could be purchased, or the increased cost of defending suits and paying claims or settlements where liability insurance was not available.

In an effort to bring vaccine prices under control and to provide fair compensation to those children who were injured by vaccines, the Congress in 1986 enacted a bill, the National Vaccine Injury Compensation Program, a no-fault administrative compensation system for children who are injured by vaccines.

And I might just digress by saying we are honored to have the author of that bill as our first witness.

I am convinced that the compensation system will provide manufacturers much relief from the liability costs that they cite as the principal reason for these increased prices. The compensation system is financed in part by surcharges which we are now collecting on all vaccine sold after January 1, 1988.

While the Congress anticipated the need for some additional funding to cover vaccine surcharges until the positive effects of the compensation system were reflected in reductions in vaccine prices, I am appalled by the response of the manufacturers to these surcharges and to the compensation system.

Two manufacturers which have been collecting their own surcharge to be used to pay vaccine injury claims have modestly reduced these internal liability charges on DPT vaccine and have thus slightly moderated the effect of the DPT surcharge.

But the manufacturer of the measles, mumps, rubella [MMR] vaccine, the Merck Corp., has actually increased the price of its vaccine and implemented the full Federal charge on MMR vaccine to boot. As a result, the price of MMR vaccine will increase by more than 50 percent from 1987 to 1988, an increase that far exceeds the vaccine surcharge and in my opinion cannot be justified.

I regret that Merck has declined the invitation to appear before this committee to explain this price increase.

What do these vaccine price increases mean for children who need immunizations and for their parents, and what do price increases mean for State governments and the Centers for Disease Control?

About one-half the children in the country receive their immunizations from private physicians and half in public clinics. The cost of a full series of vaccines in the private sector has increased from $23.29 in 1982 to $97.19 in 1987, to $117.06 in 1988, a 600-percent increase in 6 years.

We anticipate an increasing number of parents will bring their children to public clinics for their shots because they will no longer be able to afford to get their children's shots from their own pediatrician. Any shifting of children into the public sector will certainly strain a system that is already struggling to keep up.

In fiscal year 1988, the CDC will use funds intended for State operations to purchase vaccines, and in 1989 the CDC proposes to shift $18 million from State operations funding and $4 million from vaccine stockpiling to fund purchases of vaccines.

While this sleight of hand allows the CDC to say we are purchasing the same number of vaccine doses with Federal funds in 1987 as in 1988, it does not mask the fact that somebody must absorb the reductions in State operations funding and that our vaccine stockpile will not reach the goal of a 6-month stockpile.

Obviously, it is the States which will absorb this reduction, and the States which supplement Federal funds with their own funds to purchase vaccines are telling us that they are already strapped because of these increased vaccine prices.

In this climate of a funding crisis, it is difficult for us to think about expanding the immunization program by adding new vaccines to the program. Yet we must do just that.

In fiscal year 1988 and 1989, we must also find a way to cover the additional cost of the new H-flu vaccine, which offers protection against bacterial meningitis to children as young as 18 months of age, an improvement over the current vaccine, which protects children 24 months of age. I do not believe the CDC budget estimate for 1989 really adequately accounts for the use of this new vaccine.

The United States can still brag that immunization levels for school aged children are 97 percent, but this masks the fact that we still have pockets of unimmunized children and we still fail to immunize many preschool children and minority children living in the inner city.

In 1985, 38.5 percent of minority children aged 1 through 4 were not fully immunized against polio and 24.8 percent of minority children were not fully immunized against DPT.

At the current pace, the United States will probably not reach the goal of having 90 percent of all our children complete the basic series of immunizations by the age of 2. In short, any complacency is misplaced. We have problems that demand our immediate attention.

Our investment in the immunization program still yields great dividends in human and monetary terms. To limit our investment would be the height of folly.

PREPARED STATEMENTS

I am going to submit the rest of my statement for the record, without objection and I also ask that Senator Weicker's opening statement be inserted at this point.

[The statement follows:]

STATEMENT OF SENATOR DALE BUMPERS

Today's hearing is to evaluate and consider suggestions for improvement of one of the most successful and cost-effective preventive health programs in this country, the childhood immunization program. I have always considered the childhood immunization program to be the best example of a good public health program -- one that prevents human disease and human suffering and also saves families, state governments, and the federal government a great deal of money.

The experience with the measles-mumps-rubella vaccine demonstrates the success of the immunization program. Since 1963, over 65 million cases of measles and 21,500 cases of mental retardation have been averted, and 6,500 children's lives have been saved as a result of measles immunization. And in the 20 years since the measles vaccine's licensure in 1963, it has saved the U.S. $5.1 billion in direct and indirect costs.

The immunization program has been so successful that Americans take its success for granted. Young pediatricians have little knowledge of childhood diseases like whooping cough, diphtheria, and polio because they have seen few or no cases. And most Americans do not remember that as recently as 1962 we had 480,000 cases of measles reported and there were probably ten times more cases that actually occurred. Many never knew about or have forgotten the 1952 polio epidemic -- 21,000 cases of paralytic polio were reported in that year. And few remember that in the 1930's there were 5,000 deaths annually from whooping cough.

A cursory look at the immunization program might lead to the conclusion that all is well in the program. For example, the immunization level for the 3.8 million children entering school in 1986 was 97%, a record high. And the Surgeon General's 1990 objectives for reported incidence of rubella, diphtheria, tetanus, and polio have already been achieved. But a closer look at the program reveals some troubling trends: (1) continued increases in vaccine prices which in turn cause shortfalls in federal and state immunization funding, (2) stagnation or decline in immunization levels for preschool children, and (3) inability to guarantee American children access to recently-developed vaccines which protect against childhood diseases.

Since 1982, we have seen the prices of vaccines skyrocket. In 1982, a DPT shot cost 37 cents in the private sector. In 1988, the same vaccine will cost $11.03, a staggering 3000% increase. In 1982, a dose of the measles-mumps-rubella vaccine cost $10.44, and in 1988 we estimate that the same vaccine will cost $27.23. Federal funding has increased from $30.4 million in Fiscal Year 81 to more than $98 million in Fiscal Year 88. Yet increases in federal funding, supplemented by increases in state funding, never match manufacturers' price increases.

Unfortunately, the childhood vaccines cause injuries to a very small number of children who take them. The pertussis part of the DTP vaccine is blamed for the vast majority of vaccine-related injuries. While most adverse reactions are mild, permanent neurological damage is caused by 1 in 310,000 doses of pertussis vaccine. Certainly those children who are injured by vaccines should be fairly compensated for the medical expenses, lost earnings, and pain and suffering associated with the injury. And vaccine research must continue in our effort to provide the safest possible pertussis vaccine.

While we must do everything possible to improve the safety of the childhood vaccines, we cannot dismiss the benefits of the current vaccines. In the early 1930's, there were approximately 200,000 cases of whooping cough and 5,000 deaths from whooping cough annually. Provisional data indicate that there were only 2,529 cases of whooping cough in 1987.

During the 1980's there has been a rapid increase in the number of injury suits filed against the manufacturers of childhood vaccines. Vaccine manufacturers told us through the 1980's that price increases could be directly attributed to the increased costs of liability insurance, when it could be purchased, or the increased costs of defending suits and paying claims or settlements if liability insurance was not available. In an effort to bring vaccine prices under control and to provide fair compensation to those children who are injured by vaccines, the Congress enacted legislation in 1986 establishing the National Vaccine Injury Compensation Program, a no-fault administrative compensation system for children who are injured by vaccines. I am convinced that the compensation system will provide manufacturers much relief from liability costs they cite as the principal reason for increased prices.

The compensation system is financed, in part, by surcharges which we are now collecting on all vaccines sold after January 1, 1988. While the Congress anticipated the need for some additional funding to cover vaccine surcharges until the positive effects of the compensation system were reflected in reductions in vaccine prices, I am appalled by the response of the manufacturers to these surcharges and to the compensation system.

Two manufacturers which have been collecting their own surcharge to be used to pay vaccine injury claims have only modestly reduced these "internal liability charges" on DTP vaccine and thus only slightly moderated the effects of the DTP surcharge. But the manufacturer of the MMR vaccine, the Merck Corporation, has actually increased the price of its vaccine and also implemented the full federal surcharge on MMR vaccine. As a result, the price of MMR vaccine will increase by more than 50% from 1987 to 1988, an increase that far exceeds the vaccine surcharge and in my opinion cannot be justified. I regret that Merck has declined the invitation to appear at this hearing to explain this price increase.

What do these vaccine price increases mean for children who need immunizations and for their parents? And what do price increases mean for state governments and the Centers for Disease Control?

About half the children in the country receive their immunizations from private physicians and half from public clinics. The cost of a full series of vaccines in the private sector has increased from $23.29 in 1982 to $97.19 in 1987 to $117.06 in 1988, a 600% increase in 6 years. We anticipate an increasing number of parents will bring their children to public clinics for their shots because they can no longer afford to go to their own pediatrician. Any shifting of children into the public sector will only strain a system that is already struggling to keep up.

In FY 88, the CDC will use funds intended for state operations to purchase vaccines. And in FY 89, the CDC proposes to shift $18 million from state operations funding and $4 million from vaccine stockpile funding to purchase vaccines. While this sleight of hand allows the CDC to say we are purchasing the same number of vaccine doses with federal funds in FY 87, FY 88, and FY 89, it does not mask the fact that somebody must absorb the reductions in state operations funding and that our vaccine stockpile will not reach the goal of a six month stockpile. Obviously, it is the states which will absorb this reduction. And the states, which supplement federal funds with their own funds to purchase vaccines, are telling us that they are already strapped because of increased vaccine prices.

In this climate of a funding crisis, it is difficult for us to think about expanding the immunization program by adding new vaccines to the program, yet we must do so. In FY 88 and FY 89 we must find a way to cover the additional costs of the new H-flu vaccine which offers protection against bacterial meningitis to children as young as 18 months, an improvement over the current vaccine which protects children 24 months of age. I do not believe the CDC budget estimate for FY 89 adequately accounts for the use of this new vaccine.

The United States can still brag that immunization levels for school-age children are 97%, but this masks the fact that we still have pockets of unimmunized children. We still fail to immunize many pre-school children and minority children living in the inner city. In 1985, 38.5 percent of minority children age 1-4 years were not fully immunized against polio, and 24.8% of minority children were not fully immunized against DTP. At the current pace, the United States will probably not reach the goal of having 90% of all children complete a basic series of immunizations by the age of two years.

In short, any complacency is misplaced. We have problems that demand our immediate attention. Our investment in the immunization program still yields great dividends in human and monetary terms. To limit our investment would be the height of folly.

I hope this hearing will answer the following questions:

1. What level of funding will be necessary in FY 88 and FY 89 to purchase the same number of vaccine doses as were purchased in FY 87? Is that number of vaccine doses adequate in view of anticipated increases in immunization case loads in the public sector?

2. How can we increase the purchasing power of state and federal immunization dollars?

3. What financial impact will the Vaccine Compensation Act have on state immunization programs?

4. Can the failure of pharmaceutical companies to lower their prices -- and the action of one company to raise prices -- be justified in light of the reduced risks to them resulting from the Vaccine Injury Compensation Act?

5. What can we expect from the manufacturers as to vaccine prices once the Vaccine Injury Compensation System is operational?

6. What is the status of research and testing of the acellular pertussis vaccine?

7. How can we improve immunization levels among pre-school children?

STATEMENT OF SENATOR LOWELL P. WEICKER

It is a pleasure to participate in this afternoon's hearing on the Federal Government's Childhood Immunization Program. I wish to commend Senator Bumpers for taking the initiative to request this hearing so that we may explore the current status of the program and the impact the development of new vaccines and enactment of new legislation may have on this program.

The Childhood Immunization Program is one of the most important programs administered by the Federal Government. With the funds from this program, the Centers for Disease Control actually prevent morbidity and mortality among America's children. This program prevents measles, rubella, mumps, polio, DPT, and H-flu. It is the perfect example of how dollars invested in prevention translate into lives saved and dollars saved in the out-years.

Unfortunately, vaccine injuries do occur and the National Childhood Vaccine Injury Act provides for a new injury compensation program that certainly requires careful attention by this subcommittee and the entire Congress. I look forward to the testimony from my good friend Congressman Waxman, the primary sponsor of the vaccine bill, and all of the other witnesses participating in today's hearing.

Once again, the administration has proposed eliminating all funds for the vaccine stockpile and has not requested enough money to meet the total cost associated with purchasing vaccines and actually administering the program. This hearing gives us an opportunity to determine what is needed to pay for a program that is the very essence of what this Government is all about—the business of life for our children.

REMARKS BY SENATOR CHILES

Senator **BUMPERS**. We have been joined by the chairman of the subcommittee, Senator Chiles of Florida. Senator Chiles, we would be glad to hear from you.

Senator **CHILES**. Thank you very much, Senator Bumpers. I am delighted to be here this afternoon and to have you chair this most important hearing.

I know we will listen to testimony about the impact of the new vaccine injury law on the childhood immunization program. We could not have a better witness to lead off than Chairman Henry Waxman, a person who has long been an advocate and a leader of legislation in this field.

Senator Bumpers, you are certainly well known as the Senate leader and advocate of the childhood immunization program. We have all benefited from your tireless efforts in making sure that this program is a success, and I know the outstanding work that you have done in this area since you came to the Senate.

Having said that, like most good ideas that we have, we get them from our wives, and so I think Betty Bumpers is the person that made you do this or got you started.

Senator **BUMPERS**. She is nodding approval back there.

Senator **CHILES**. I know you could not sleep at night unless you were championing this program that she started out.

With the passage of the vaccine compensation amendments in last year's reconciliation bill, we are faced with some anticipated funding gaps, and I certainly share your interest, Senator Bumpers, in finding out what the additional requirements are and what we can do about them.

As a participant in last year's budget agreement, I guess I would be remiss if I did not acknowledge that we did make a bipartisan agreement there would be no supplemental in 1988. And so any supplemental that we do have has to be deficit-neutral. That gives us another problem as we try to work into where we find these funds.

But I want to compliment you for your effective leadership, and I am delighted that you are holding these hearings.

Senator BUMPERS. Thank you very much, Mr. Chairman.

And Chairman Waxman, we are most happy to have you as our leadoff witness. Please proceed.

STATEMENT OF HON. HENRY A. WAXMAN, U.S. REPRESENTATIVE FROM CALIFORNIA

Mr. WAXMAN. Thank you very much, Senator Bumpers, Senator Chiles. I am delighted to be here to share my thoughts with you.

Mr. Chairman, I could not say it any better than you presented the case to us in your opening statement, but let me say it again in my comments to you. There is nothing more valuable by way of a contribution that the Federal Government makes to children's health than immunizations.

And I do want to take a moment to acknowledge the role that this committee and that you, Mr. Chairman, and your wife have played in this program, the important role you have played to make this program work.

The open-handed generosity of this committee has kept the efforts to protect children, going through a period of waxing inflation, that has added up to thousands of percent. The care that you and your staff have taken in making sure that this program is neither overlooked nor taken for granted has ensured the safety of millions of children.

Simply put, the immunization program works. Not so long ago, polio terrorized the country every summer, panicking parents and crippling children. Now it is not even a household word.

In recent memory, measles and the disabilities it can cause were common. Now a measles outbreak makes headlines. As legislators, we can be proud that much of that change comes from Federal and State programs to get children immunized.

As taxpayers and budgetmakers, we can feel accomplishment at the millions of dollars that are saved by preventing disease, disability, and death. But we cannot allow ourselves to feel complacent that we have finished the job.

To work well, there must always be four component parts of the Federal immunization program: the purchase of vaccine, the administration of shots, the compensation of children injured by vaccines, and the stockpiling of emergency supplies of vaccine.

If adequately funded, these components work together to protect the Nation from preventable disease. In addition to the human tragedy, sick children are a drain on acute health care dollars, may become permanently disabled and be a drain on long-term health care dollars and may become less productive citizens and be a drain on the tax base and the economy.

If we prevent even a small percentage of these illnesses, we will more than make up for the initial cost of immunization. If our commitment to children is to be more than empty sentiment, we must make this investment.

If, however, any of these parts is unaddressed, immunization efforts may fail. If for example there is a shortage of vaccine, no grant program can instantly produce a stockpile. Or if there is a shortfall in funds to vaccinate, all the vaccine purchased will be for nought.

This is why the Reagan administration's 8 years of nickeling and diming the program is so dangerous. Each budget game, each fake assumption, each winking at the inflation rate means that children somewhere are not being immunized, and that we will all be poorer for it the next year or the year after, whenever measles or pertussis comes back again.

It is for this reason that we cannot allow the Reagan administration to play the shell game contained in its 1989 budget. In its press releases, the administration piously claims to provide enough money to purchase the same amount of vaccine as last year. In the fine print of the budget documents, however, we find that they do so only by eliminating the programs to administer the shots and stockpile emergency vaccines.

It is a proposal to manufacture cars, but save money by leaving off the wheels. Instead of this dodging of opportunity, we should be expanding immunization to find the children who remain unimmunized or who are immunized long after they should be.

We should offer immunizations on every corner. There should be vaccines at every clinic, nurses at every preschool, and information at every grocery store. Instead of looking for ways to cut corners and limit availability, we should be looking for the immunization simplification program.

We should study the models in Vermont and North Dakota, where the States buy vaccine and give it away, keeping costs low and access high. We should study universal Federal programs of vaccine purchase, complemented by assistance to State and local governments for the administration of the shots.

It is not always easy. Vaccine prices are products of monopoly, cartels, and black boxes. Parental procrastination often prevents vaccination until the law requires it for school, well beyond the time it may be needed for protection.

But we cannot allow children to die of diseases that should never occur, and we cannot afford to treat children for crippling conditions that we can prevent. CDC reports that almost no parents decline immunization if it is offered for their child. We must offer it for everyone.

In closing, let me make a special request for the committee's consideration of the funding of the compensation program for children who were injured before the effective date of the law, the so-called retroactive cases.

It was with great reluctance that the Health Subcommittee in the House moved to separate these children from the trust fund created by excise taxes. But it was necessary to do so in order to keep the trust fund solvent and the excise tax affordable.

I do not believe, however, that the result must be that these children have no government-funded recourse for their injuries. They and their families have undertaken vaccination because it was recommended, often required, and because it was deemed to be in the best interest of the Nation's health.

They have been injured in that course. They have a legitimate claim on us, not for economic reasons or for pricing structures or for future vaccine supply, but for fairness.

I would ask that as you look at the appropriations for this and next year that you remember that claim and provide funding for compensation for these cases.

PREPARED STATEMENT

I thank you for the opportunity to be here and I will be pleased to answer any questions.

[The statement follows:]

STATEMENT OF HON. HENRY A. WAXMAN

I APPRECIATE THE OPPORTUNITY TO APPEAR BEFORE THIS COMMITTEE TODAY TO TALK ABOUT WHAT IS PERHAPS THE MOST VALUABLE CONTRIBUTION THAT THE FEDERAL GOVERNMENT MAKES TO CHILDREN'S HEALTH--IMMUNIZATIONS.

FIRST, I WANT TO TAKE A MOMENT TO ACKNOWLEDGE THE ROLE THAT THIS COMMITTEE AND THAT YOU, MR. CHAIRMAN, HAVE PLAYED IN MAKING THIS PROGRAM WORK. THE OPEN-HANDED GENEROSITY OF THIS COMMITTEE HAS KEPT THE EFFORTS TO PROTECT CHILDREN GOING THROUGH A PERIOD OF VACCINE INFLATION THAT HAS ADDED UP IN THE THOUSANDS OF PERCENT. THE CARE THAT YOU AND YOUR STAFF HAVE TAKEN IN MAKING SURE THAT THIS PROGRAM IS NEITHER OVERLOOKED NOR TAKEN FOR GRANTED HAS ENSURED THE SAFETY OF MILLIONS OF CHILDREN.

SIMPLY PUT, THE IMMUNIZATION PROGRAM WORKS.

NOT SO LONG AGO, POLIO TERRORIZED THE COUNTRY EVERY SUMMER, PANICKING PARENTS AND CRIPPLING CHILDREN. NOW IT IS NOT EVEN A HOUSEHOLD WORD.

IN RECENT MEMORY, MEASLES AND THE DISABILITIES IT CAN CAUSE WERE COMMON. NOW A MEASLES OUTBREAK MAKES HEADLINES.

AS LEGISLATORS, WE CAN BE PROUD THAT MUCH OF THAT CHANGE COMES FROM FEDERAL AND STATE PROGRAMS TO GET CHILDREN IMMUNIZED. AS TAXPAYERS AND BUDGETMAKERS WE CAN FEEL ACCOMPLISHMENT AT THE MILLIONS OF DOLLARS THAT ARE SAVED BY PREVENTING DISEASE, DISABILITY, AND DEATH.

BUT WE CANNOT ALLOW OURSELVES TO FEEL COMPLACENT THAT WE'VE FINISHED THE JOB. TO WORK WELL, THERE MUST ALWAYS BE FOUR COMPONENT PARTS OF THE FEDERAL IMMUNIZATION PROGRAM:

THE PURCHASE OF VACCINE,
THE ADMINISTRATION OF SHOTS,
THE COMPENSATION OF CHILDREN INJURED BY VACCINES, AND
THE STOCKPILING OF EMERGENCY SUPPLIES OF VACCINE.

IF ADEQUATELY FUNDED, THESE COMPONENTS WORK TOGETHER TO PROTECT THE NATION FROM PREVENTABLE DISEASE. IN ADDITION TO THE HUMAN TRAGEDY, SICK CHILDREN ARE A DRAIN ON ACUTE HEALTH CARE DOLLARS, MAY BECOME PERMANENTLY DISABLED AND BE A DRAIN ON LONG-TERM HEALTH CARE DOLLARS, AND MAY BECOME LESS PRODUCTIVE CITIZENS AND BE A DRAIN ON THE TAX BASE AND THE ECONOMY. IF WE PREVENT EVEN A SMALL PERCENTAGE OF THESE ILLNESSES, WE WILL MORE THAN MAKE UP FOR THE INITIAL COSTS OF IMMUNIZATION. IF OUR COMMITMENT TO CHILDREN IS TO BE MORE THAN EMPTY SENTIMENT, WE MUST MAKE THIS INVESTMENT.

IF, HOWEVER, ANY OF THESE PARTS IS UNADDRESSED, IMMUNIZATION EFFORTS MAY FAIL. IF, FOR EXAMPLE, THERE IS A SHORTAGE OF VACCINE, NO GRANT PROGRAM CAN INSTANTLY PRODUCE A STOCKPILE. OR IF THERE IS A SHORTFALL IN FUNDS TO VACCINATE, ALL THE VACCINE PURCHASED WILL BE FOR NAUGHT.

THIS IS WHY THE REAGAN ADMINISTRATION'S EIGHT YEARS OF NICKLING AND DIMING THE PROGRAM IS SO DANGEROUS. EACH BUDGET GAME, EACH FAKE ASSUMPTION, EACH WINKING AT THE INFLATION RATE MEANS THAT CHILDREN SOMEWHERE ARE NOT BEING IMMUNIZED AND THAT WE WILL ALL BE POORER FOR IT NEXT YEAR OR THE YEAR AFTER, WHENEVER MEASLES OR PERTUSSIS COMES BACK AGAIN.

IT IS FOR THIS REASON THAT WE CANNOT ALLOW THE REAGAN ADMINISTRATION TO PLAY THE SHELL GAME CONTAINED IN ITS 1989 BUDGET. IN ITS PRESS RELEASES, THE ADMINISTRATION PIOUSLY CLAIMS TO PROVIDE ENOUGH MONEY TO PURCHASE THE SAME AMOUNT OF VACCINE AS LAST YEAR. IN THE FINE PRINT OF THE BUDGET DOCUMENTS, HOWEVER, WE FIND THAT THEY DO SO ONLY BY ELIMINATING THE PROGRAMS TO ADMINISTER THE SHOTS AND STOCKPILE EMERGENCY VACCINES. IT IS A PROPOSAL TO MANUFACTURE CARS BUT SAVE MONEY BY LEAVING OFF THE WHEELS.

INSTEAD OF THIS DODGING OF OPPORTUNITY, WE SHOULD BE EXPANDING IMMUNIZATION TO FIND THE CHILDREN WHO REMAIN UNIMMUNIZED OR WHO ARE IMMUNIZED LONG AFTER THEY SHOULD BE. WE SHOULD OFFER IMMUNIZATIONS ON EVERY CORNER. THERE SHOULD BE VACCINE AT EVERY CLINIC, NURSES AT EVERY PRE-SCHOOL, AND INFORMATION AT EVERY GROCERY STORE.

INSTEAD OF LOOKING FOR WAYS TO CUT CORNERS AND LIMIT AVAILABILITY, WE SHOULD BE LOOKING FOR THE IMMUNIZATION SIMPLIFICATION PROGRAM. WE SHOULD STUDY THE MODELS IN VERMONT AND NORTH DAKOTA, WHERE THE STATES BUY VACCINE AND GIVE IT AWAY, KEEPING COSTS LOW AND ACCESS HIGH. WE SHOULD CONSIDER UNIVERSAL FEDERAL PROGRAMS OF VACCINE PURCHASE, COMPLEMENTED BY ASSISTANCE TO STATES AND LOCAL GOVERNMENTS FOR THE ADMINISTRATION OF THE SHOTS.

IT ISN'T ALWAYS EASY. VACCINE PRICES ARE PRODUCTS OF MONOPOLY, CARTELS, AND BLACK BOXES. PARENTAL PROCRASTINATION OFTEN PREVENTS VACCINATION UNTIL THE LAW REQUIRES IT FOR SCHOOL--WELL BEYOND THE TIME IT MAY BE NEEDED FOR PROTECTION.

BUT WE CANNOT ALLOW CHILDREN TO DIE OF DISEASES THAT SHOULD NEVER OCCUR, AND WE CANNOT AFFORD TO TREAT CHILDREN FOR CRIPPLING CONDITIONS THAT WE CAN PREVENT. CDC REPORTS THAT ALMOST NO PARENTS DECLINE IMMUNIZATION IF IT IS OFFERED FOR THEIR CHILD. WE MUST OFFER IT TO EVERYONE.

IN CLOSING, LET ME MAKE A SPECIAL REQUEST FOR THE COMMITTEE'S CONSIDERATION OF THE FUNDING OF THE COMPENSATION PROGRAM FOR CHILDREN WHO WERE INJURED BEFORE THE EFFECTIVE DATE OF THE LAW, THE SO-CALLED "RETROACTIVE CASES." IT WAS WITH GREAT RELUCTANCE THAT THE HEALTH SUBCOMMITTEE MOVED TO SEPARATE THESE CHILDREN FROM THE TRUST FUND CREATED BY EXCISE TAXES, BUT IT WAS NECESSARY TO DO SO IN ORDER TO KEEP THE TRUST FUND SOLVENT AND THE EXCISE TAX AFFORDABLE. I DO NOT BELIEVE, HOWEVER, THAT THE RESULT MUST BE THAT THESE CHILDREN HAVE NO GOVERNMENT-FUNDED RECOURSE FOR THEIR INJURIES. THEY AND THEIR FAMILIES HAVE UNDERTAKEN VACCINATION BECAUSE IT WAS RECOMMENDED--OFTEN REQUIRED--AND BECAUSE IT WAS DEEMED TO BE IN THE BEST INTEREST OF THE NATION'S HEALTH. THEY HAVE BEEN INJURED IN THAT COURSE. THEY HAVE A LEGITIMATE CLAIM ON US, NOT FOR ECONOMIC REASONS OR FOR PRICING STRUCTURES OR FOR FUTURE VACCINE SUPPLY, BUT FOR FAIRNESS. I WOULD ASK THAT AS YOU LOOK AT THE APPROPRIATIONS FOR THIS AND NEXT YEAR THAT YOU REMEMBER THAT CLAIM AND PROVIDE FUNDING FOR COMPENSATION FOR THESE CASES.

THANK YOU FOR THE OPPORTUNITY TO BE HERE.

Senator BUMPERS. Chairman Waxman, thank you very much for a very fine statement.

As you know, we have a rollcall vote on right now and I think I have about 1 minute. I would just like to ask you this question before we have to quit for about 5 minutes.

Apparently there is an assumption on the part of most of the manufacturers that one-half of the people who have compensable claims as a result of an injury related to a child vaccine like DTP will reject the administrative process of the vaccine compensation law and file suit under the tort system.

Do you think that is a fair assumption or not?

Mr. WAXMAN. No; I do not think that is a fair assumption. If the program works as we intend it, and I think it will work, we have a no fault compensation system and those children that are injured will seek recourse through that compensation system without going to court.

They have the option after they have gone through the compensation system, if they feel that they want to waive that allotment of funds to them and then pursue a case in court.

But I just do not believe as a practical matter they are going to do that. I think what we have is a fair compensation system. People are going to accept it, and as a result we will see fewer lawsuits. With fewer lawsuits, we will see less reserves being put aside to protect the manufacturer from the liability claims, and as a result I think even a lower price for vaccines is something we can predict in the years ahead.

Senator BUMPERS. Representatives of Lederle Labs are with us here today, and we applaud them coming here to discuss vaccine prices and the whole problem of immunizating our children. I thank them very much for coming.

I want to ask you one question. Lederle Labs has reduced the price of the internal surcharge that it has been collecting to pay damages to children who have compensable injuries.

Do you think Lederle has reduced its internal surcharges enough by reducing them roughly, 50 percent? Do you think that reduction is sufficient?

Now, you understand of course Lederle is collecting the Federal surcharge on DTP that exceeds $4 per dose.

Mr. WAXMAN. I think it indicates that they expect that the fund is not going to be necessary for them to collect to protect themselves from private liability if we have this compensation fund.

I cannot tell you whether it is enough because we do not know yet if the program is going to be as successful as we predict. But I think the program that we designed is one that will steer injured children and their families to the compensation system and away from court actions.

We have even restricted the tort action standards to limit court claims if they refuse to go along with the compensation itself. I think we have created a system that will by and large mean that most cases will go to the compensation fund, be satisfied out of that fund, and therefore there will not be the need for the companies to have an extra charge on the vaccines to protect themselves from the liability claims that they fear that will come about if there are court actions.

Senator BUMPERS. Henry, thank you very much for coming here this afternoon.

We will stand in recess for 5 minutes while Senator Chiles and I vote.

[A brief recess was taken.]

STATEMENT OF DR. JAMES MASON, DIRECTOR, CENTERS FOR DISEASE CONTROL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

ACCOMPANIED BY DR. ALAN HINMAN, DIRECTOR, CENTER FOR PREVENTION SERVICES, CENTERS FOR DISEASE CONTROL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator WEICKER [presiding]. The committee will come to order.

The next witness is Dr. James Mason, who is Director of the Centers for Disease Control [CDC].

Incidentally, I want the record to include my opening statement following that of Senator Bumpers, and ask unanimous consent that that be done.

Dr. Mason of course is well known to this Senator as a very able and capable Director of the Centers for Disease Control, an institution we are all very proud of. And in all the difficulties that face this Nation in terms of science and medicine, it is always good to know that we have a component of such capacity and integrity at the centers.

So it is nice to have you before the committee, Dr. Mason, and we look forward to your testimony. And your testimony in its entirety will be included in the record.

Dr. MASON. Thank you very much, Senator Weicker. We appreciate your kind words.

I am accompanied by Dr. Alan Hinman, who is the Director of the Center for Prevention Services at CDC. Dr. Hinman also serves as coordinator of the national vaccine program, which is under the direction of the Assistant Secretary for Health.

We appreciate the opportunity to discuss the present status of our national childhood immunization program and the impact on this program of the National Childhood Vaccine Injury Compensation Act.

In Senator Bumpers' letter of invitation, six questions were raised, to which I will respond in turn. First, however, I would like to give a brief summary of childhood immunizations in the United States and recent events with regard to vaccine price and vaccine liability.

Eight toxoids and vaccines are currently recommended by the American Academy of Pediatrics and the PHS Immunization Practices Advisory Committee for all infants and children in the United States. The recommended schedule for administration of these vaccines is shown in attachment 1 of our testimony. Introduction and widespread use of these vaccines has had a dramatic effect on the occurrence of disease, with reductions in occurrence of 90 percent or greater.

Children may receive immunizations in the office of a private physician or from a local health department or community health center. Nationwide, we estimate that approximately 50 percent of infants receive their immunizations in private offices and the remainder in public health clinics.

Since 1963, Federal grant support has been provided to State and local health departments to help provide these public sector immunizations. The Federal support has provided both vaccines and nonvaccine services, such as surveillance, assessment, outreach, education, and evaluation.

States purchase vaccines using awarded immunization grant funds at a considerable savings compared to the private sector cost through the use of Federal consolidated contracts, as shown in attachment 3.

In recent years there have been major escalations in the cost of vaccines in both the private and public sectors. These price increases have been attributed at least in part to the rapid increase in liability claims filed against vaccine manufacturers.

The enactment of the excise tax on vaccines to establish a trust fund for the vaccine injury compensation program had an immediate effect on the prices paid for vaccines. Our attachment 8 shows the change in price that occurred on implementation of the excise tax on January 1, 1988.

These price increases have been accommodated within the President's fiscal year 1989 budget.

With this background, I would now like to turn to the specific questions that were raised in the letter of invitation: First, what level of funding will be necessary in fiscal years 1988 and 1989 to purchase the same number of vaccine doses as were purchased in fiscal year 1987? In this presentation I will not address vaccines purchased in the private sector, nor vaccines purchased in the public sector using State or local funds.

It is estimated that $77.3 million will be required in fiscal year 1988 to provide the same number of doses of vaccine as were purchased in 1987. In 1989, the estimated cost will be $92.8 million.

These amounts are covered in the fiscal year 1988 appropriation and in the President's budget request for fiscal year 1989.

Question two. Is the number of doses adequate to serve the current population of children? The size of the birth cohort, approximately 3.8 million annual births, is not changing dramatically, and the number of doses projected should be adequate, providing there is no major change in the proportion of children seeking immunizations in the public as compared to the private sector. There is no evidence to suggest that such a change is occurring.

Question three. What is the current status of the vaccine stockpile? By the end of fiscal year 1988, it is estimated that OPV, MMR, DT, and Td stockpiles will contain approximately a 21-week supply, the IPV stockpile will have a 17-week supply, and the DTP stockpile will have approximately a 15-week supply. That is illustrated in attachment 9.

There is an error in attachment 9 in that the vaccine ordered for the IPV stockpile but not yet delivered is not shown.

Question four. Are we aware or do we anticipate an increased demand for immunizations through public sector clinics because of the increased prices of vaccines? We are aware that concern has been expressed that the rising cost of vaccines could lead to a shift from the private to the public sector.

To date we have seen no concrete evidence of such a shift. Attachment 10 depicts DTP vaccine administration in public clinics as a proportion of total DTP vaccine distribution in the United States from 1980 through 1987—for the first three quarters of 1987. Attachment 11 depicts the same information for OPV, and attachment 12 for measles vaccine.

Question five. How can we correct the recent decline in immunization rates among preschool aged children? Even though immunization levels are not as high as we would like for preschool aged children, there are no data to indicate that there has been a statistically significant decline in the immunization levels for this age group since 1981.

Our current estimate is that 75 to 85 percent of preschoolers nationwide are completely immunized. However, it is quite clear that in some inner city areas the proportion fully immunized is lower than that figure.

In contrast, reports from States on preschool children attending Head Start centers or licensed day care centers indicate that approximately 90 percent are immunized. At the time of entry to school, more than 97 percent of children have been immunized.

For the 1986–87 school year, the immunization level of entering kindergarten-first grade students was 97 percent, the highest ever.

Question six: Why was the U.S. immunization survey discontinued and what would be the cost of reinstituting this survey or a comparable annual survey? The U.S. immunization survey was discontinued in 1985 when it became apparent that the data obtained from this telephonic household survey were inadequate to be used for programmatic decisionmaking.

We feel assessment data from individual States more accurately reflect the true immunization status of the Nation. We are exploring ways in which we can obtain reliable estimates of the immunization levels in preschoolers.

In conclusion, great progress has been made in the control of childhood diseases through the use of vaccines, and the Federal Government has played an important part in this progress through the immunization grant program.

PREPARED STATEMENT

This concludes my prepared testimony. Dr. Hinman and I would be happy to answer any questions.

[The statement follows:]

STATEMENT OF JAMES O. MASON

I am Dr. James O. Mason, Director of the Centers for Disease Control (CDC). I am accompanied by Dr. Alan Hinman, Director of the Center for Prevention Services at CDC. Dr. Hinman also serves as Coordinator of the National Vaccine Program, which is under the direction of Dr. Robert E. Windom, Assistant Secretary for Health.

I appreciate the opportunity to discuss the present status of our national childhood immunization program and the impact on this program of the National Childhood Vaccine Injury Compensation Act. Subtitle II of this Act becomes effective on October 1, 1988, now that an excise tax on vaccines has been enacted as part of the Omnibus Budget Reconciliation and Appropriatiou Act of 1987 (PL 100-203), approved December 22, 1987. The tax has been in effect for vaccines purchased on or after January 1, 1988.

In your letter of invitation, you raised six specific questions to which I will respond in turn. First, however, I would like to give a brief summary of childhood immunizations in the United States and recent events with regard to vaccine price and vaccine liability. Let me also say that the immunization programs, including Federal immunization grants, continue to be successful.

Eight toxoids and vaccines are currently recommended by the American Academy of Pediatrics and the PHS Immunization Practices Advisory Committee (ACIP) for all infants and children in the United States: diphtheria and tetanus toxoids; pertussis, oral poliovirus, measles, mumps, rubella, and Haemophilus influenzae type b (Hib) conjugate vaccines. The recommended schedule for administration of these vaccines is shown in Attachment 1. Introduction and widespread use of these vaccines has had a dramatic effect on the occurrence of disease, with reductions in occurrence of 90 percent or greater (Attachment 2). Dramatic reductions have been seen in the reported incidence of each of these diseases. In fact, the 1990 Health Objectives for the Nation for reported incidence of rubella, diphtheria, tetanus, and polio have already been achieved. Since the Hib vaccine has only recently been introduced, detailed data are not available on its impact.

Children may receive immunizations in the office of a private physician or from a local health department or community health center. Nationwide, we estimate that approximately 50 percent of infants receive their immunizations in private offices and the remainder in public clinics. Since 1963, Federal grant support has been provided to State and local health departments to help provide these public sector immunizations. The Federal support has provided both vaccines and non-vaccine services such as surveillance, assessment, outreach, education, and evaluation. States purchase vaccines using awarded immunization grant funds at a considerable savings compared to the private sector cost through use of Federal consolidated contracts (Attachment 3). It should be noted that the CDC immunization grant program provides approximately 50 percent of the cost of vaccines delivered in the public sector; the remainder comes from State and local appropriations or other Federal sources such as Medicaid, Maternal and Child Health, Community Health Centers, and the Indian Health Service programs.

In recent years, there have been major escalations in the costs of vaccines in both the private and public sectors. Attachments 4, 5, and 6 show the change in prices in the public and private sectors of diphtheria and tetanus toxoids with pertussis vaccine (DTP), oral polio vaccine (OPV), and (measles, mumps and rubella (MMR) vaccine, respectively. These price increases have been attributed, at least in part, to the rapid increase in liability claims filed against vaccine manufacturers. The number of suits brought against the manufacturers of DTP vaccines began a dramatic increase in 1982 and reached a peak in 1986, when 255 suits were brought (Attachment 7). This number declined somewhat in 1987, to 178 suits. In approximately 53 percent of suits, an amount sought is specified. In 1987, 96 suits specified an amount sought, and the total sought in these suits was more than $1.3 billion.

The enactment of the excise tax on vaccines to establish a trust fund for the Vaccine Injury Compensation Program had an immediate effect on the prices paid for vaccines. Attachment 8 shows the change in price that occurred on implementation of the excise tax, January 1, 1988. The overall price increase in DTP vaccine was less than the $4.56/dose excise tax since the manufacturers lowered the amount of their internal liability set-aside. In addition, Lederle absorbed the $0.29/dose excise tax in its existing price for OPV. By contrast, Merck raised the private sector price of MMR by some 25 percent and then added the excise tax on top of that, the net effect being an increase in cost of MMR vaccine from $22.79/dose to $27.23/dose. The public sector price was increased by the amount of the excise tax on January 1, 1988, and increased by an additional 10 percent of base cost on February 25, 1988, resulting in a net increase from $10.67/dose to $16.18/dose. These price increases have been accommodated within the President's FY 1989 Budget.

With this background, I would now like to turn to the specific questions you raised in your letter of invitation.

1. What level of funding will be necessary in FY 1988 and FY 1989 to purchase the same number of vaccine doses as were purchased in FY 1987?

   In this presentation I will not address vaccines purchased in the private sector nor vaccines purchased in the public sector using state or local funds. Looking only at the vaccine provided through the Federal CDC immunization program which is approximately 50% of public sector vaccine purchased, it is estimated that $77.3 million will be required in FY 1988 to provide the same number of doses of vaccine as were purchased in FY 1987. In FY 1989, the estimated cost will be $92.8 million. These estimates include excise taxes of approximately $19 million in FY 1988 and almost $26 million in FY 1989. These amounts are covered in the FY 1988 appropriation and in the President's Budget request for FY 1989. These cost estimates were based on known or projected changes in price for DTP, OPV, MMR, and Hib.

2. Is that number of doses adequate to serve the current population of children?

   The size of the birth cohort (approximately 3.8 million annual births) is not changing dramatically, and the number of doses projected should be adequate, providing there is no major change in the proportion of children seeking immunizations in the public as compared to the private sector. There is no evidence to suggest that such a change will occur.

3. What is the current status of the vaccine stockpile?

By the end of FY 1988, it is estimated that the OPV, MMR, DT, and Td stockpiles will contain approximately a 21 week supply, the IPV stockpile will have a 17 week supply, and the DTP stockpile will have approximately a 15 week supply (Attachment 9). Overall, we have spent $27.6 million on the stockpile.

4. Are you aware of or do you anticipate an increased demand for immunizations through public sector clinics because of increased prices of vaccines?

Based on 1986 data, we estimate that the public sector programs, which are supported by Federal, State, and local resources, will continue to provide approximately 50 percent of the vaccine administered in the United States. Our estimates for FY 88 and FY 89 assume that this distribution pattern will continue. We are aware that concern has been expressed that the rising cost of vaccines could lead to a shift from the private to the public sector. To date, we have seen no concrete evidence of such a shift. Attachment 10 depicts DTP vaccine administration in public clinics as a proportion of total DTP vaccine distribution in the United States from 1980 through 1987 (first three quarters). Attachment 11 depicts the same information for OPV and Attachment 12 for measles vaccine. Attachment 13 summarizes the information for the three vaccines.

5. How can we correct the recent decline in immunization rates among pre-school age children?

Even though immunization levels are not as high as we would like for pre-school age children, there are no data to indicate that there has been a statistically significant decline in the immunization levels for this age group since 1981. Moreover, we have continued to achieve record low numbers of many infectious diseases among children. Our current estimate is that 75-85 percent of preschoolers nationwide are completely immunized. However, it is clear that in some inner-city areas the proportion fully immunized is lower than that figure. In contrast, reports from States on preschool children attending Headstart centers or licensed day-care centers indicate that approximately 90 percent are immunized. At the time of entry to school, more than 95 percent of children have been immunized. For the 1986-87 school year, the immunization level of entering kindergarten-first grade students was 97 percent, the highest ever.

Preschool immunization levels are lowest, and most of the cases of the vaccine-preventable diseases in preschool populations occur, in the lower socioeconomic areas of about 20 counties in the United States. We are attempting to find effective ways to motivate parents in these areas to take advantage of the vaccines which are available through CDC's immunization grant funds, Medicaid, MCH, and other public and private sources.

6. Why was the United States Immunization Survey discontinued and what would be the cost of reinstituting this survey or a comparable annual survey?

The United States Immunization Survey (USIS) was discontinued in 1985 when it became apparent that the data obtained from this telephonic household survey were inadequate to be used for programmatic decision making and could only be used as a broad indicator of a major change in the National immunization level. We feel assessment data from individual States more accurately reflect the true immunization status of the Nation. We are exploring ways in which we can obtain reliable estimates of the immunization levels in preschoolers.

In conclusion, Mr. Chairman, great progress has been made in the control of childhood diseases through the use of vaccines, and the Federal Government has played an important part in this progress through the Immunization Grant program. This concludes my prepared testimony. I would be happy to answer any questions.

ATTACHMENT 1

Routine Pediatric Immunization Schedule

Age	Antigens
2 months	DTP–1, OPV–1
4 months	DTP–2, OPV–2
6 months	DTP–3
15 months	MMR, DTP–4, OPV–3
18 months	Hib conj.
4–6 years	DTP–5, OPV–4
15 years (every 10 years thereafter)	Td

ATTACHMENT 2

Comparison of Maximum and Current Morbidity Vaccine–Preventable Diseases

	Maximum cases	(Year)	1987 (Prov.)	Percent Change
Diphtheria	206,939	(1921)	3	– 99.999
Measles	894,134	(1941)	3,588	– 99.60
Mumps*	152,209	(1968)	12,299	– 91.92
Pertussis	265,269	(1934)	2,529	– 99.05
Polio (paralytic)	21,269	(1952)	0	–100.00
Rubella+	57,686	(1969)	329	– 99.43
CRS	20,000+	(1964–5)	5	– 99.98
Tetanus§	601	(1948)	40	– 93.34

*First reportable in 1968

+First reportable in 1966

§First reportable in 1947

ATTACHMENT 3

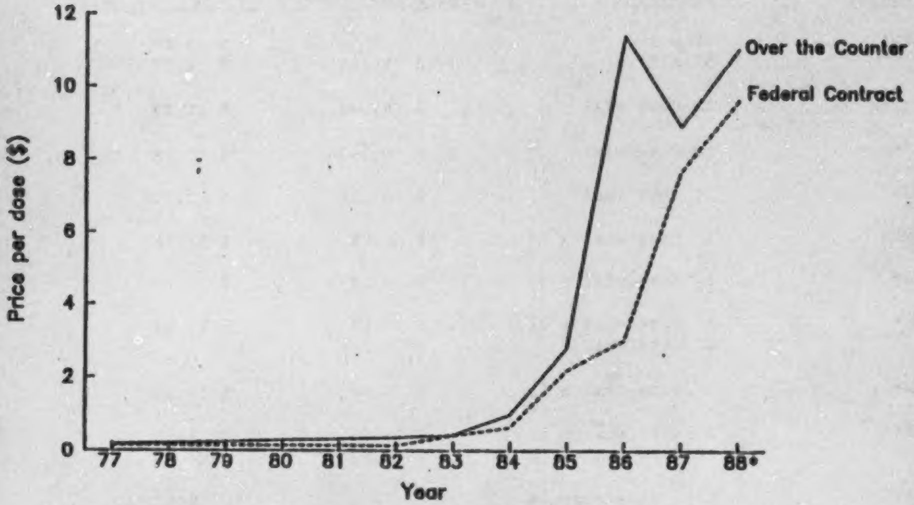
Vaccine Prices
Current as of March 2, 1988

Vaccine or Product	Packaging	CDC Contract Price (Per Dose)	Representative Catalog Price (Per Dose)
OPV*	10 x 1	-	$ 8.67
	50 x 1	$ 1.363	$ 8.07
DTP*	15 dose vial	$ 9.623	$ 11.03
DT*	10 dose vial	$ 0.193	$ 0.78
Td*	10 dose vial	$ 0.156	$ 0.78
MMR*	1 dose vial x 10	$ 16.18	$ 27.23
Me*	1 dose vial x 10	$ 9.19	$ 13.79
Mu*	1 dose vial x 10	$ 11.01	$ 15.26
	10 dose vial	$ 9.366	
Ru*	1 dose vial x 10	$ 8.88	$ 14.24
MR*	1 dose vial x 10	$ 11.65	$ 19.55
	10 dose vial	$ 9.83	-
IPV	1 ml dose ampoule x 5	-	$ 8.82
IPV	0.5 ml dose ampoule x 5	-	$ 13.00 (Estimated-scheduled to be available April 1, 1988.)
Haemophilus b Polysaccaride Vaccine	1 dose vial x 5	$ 2.17**	$ 7.55
	5 dose vial	-	$ 6.68
	10 dose vial	-	$ 6.68
Haemophilus b Conjugate	1 dose vial x 5	-	$ 15.75
	5 dose vial	-	$ 13.75
	10 dose vial	-	$ 13.75
Pneumococcal Vaccine	1 dose syringe x 5	$ 3.57**	$ 9.25
	5 dose vial	$ 2.942**	$ 8.25
Meningococcal Quadvalent (A,C,Y,W135)	10 dose vial	-	$ 8.51
Yellow Fever	1 dose vial x 5	-	$ 16.91
	5 dose vial	-	$ 8.07
Influenza	10 dose vial	-	$ 2.50
Hepatitis B (Recombinant) -	3 dose vial	-	$ 41.33 Adult
	1 dose vial	-	$ 33.09 Pediatric
Hepatitis B Immune Globulin	5 ml vial	-	$235.24 per vial

*Prices include Federal excise tax.
**These prices may change within the next 60 days. New contracts are being negotiated.

ATTACHMENT 4

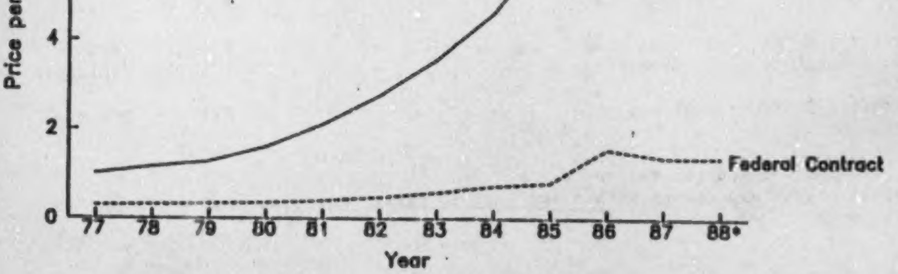
DTP Vaccine, U.S. Prices
1977–1988



* Prices Include Federal Excise Tax.

ATTACHMENT 5

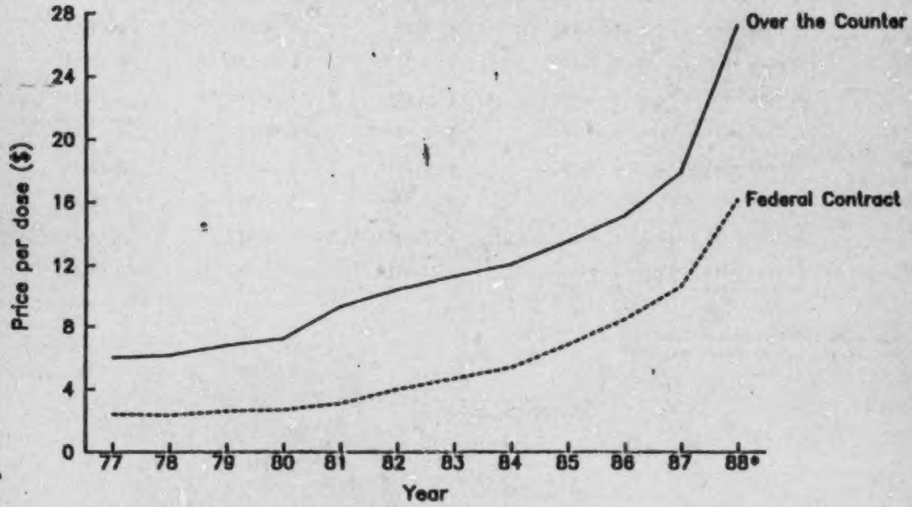
OPV Vaccine, U.S. Prices
1977–1988



* Price Includes Federal Excise Tax.

ATTACHMENT 6

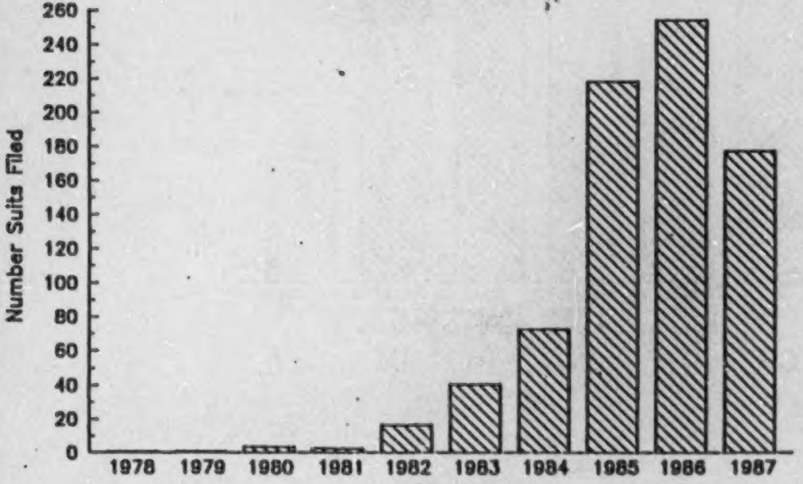
MMR Vaccine, U.S. Prices
1977–1988



*Prices include Federal Excise Tax.

ATTACHMENT 7

DTP Suits Filed
U.S.A., 1978–1987



ATTACHMENT 8

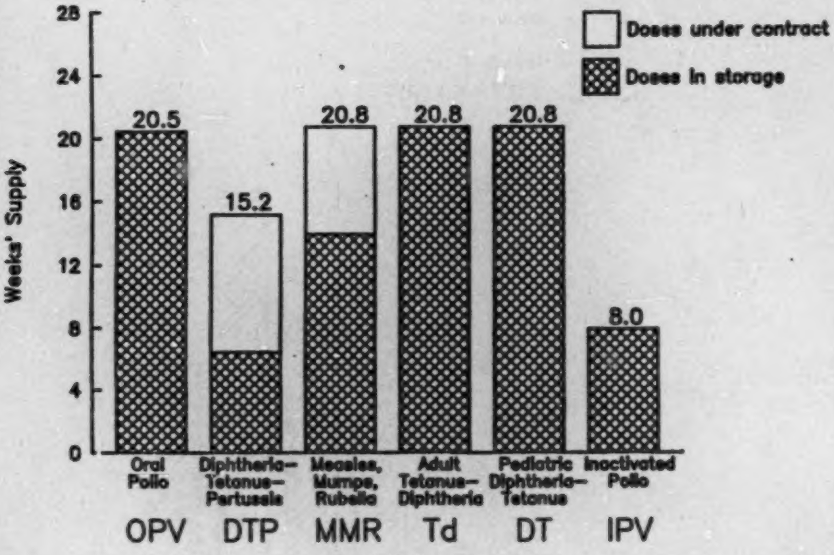
Vaccine Prices
December 31, 1987 vs. March 1, 1988

		12/31/87		3/1/88	
Vaccine or Product	Packaging	CDC Contract Price (Per Dose)	Private Sector Price (Per Dose)	CDC Contract Price (Per Dose)	Private Sector Price (Per Dose)
OPV	50 x 1	$ 1.363	$ 8.07	$ 1.363	$ 8.07
DTP	15 dose vial	$ 7.693	$ 8.92	$ 9.623	$ 11.03
DT	10 dose vial	$ 0.133	$ 0.72	$ 0.193	$ 0.78
Td	10 dose vial	$ 0.096	$ 0.652	$ 0.156	$ 0.78
MMR	1 dose vial x 10	$ 10.67	$ 17.88**	$ 16.18	$ 27.23
Me	1 dose vial x 10	$ 4.32	$ 6.74**	$ 9.19	$ 13.79
Mu	1 dose vial x 10	$ 5.97	$ 8.80**	$ 11.01	$ 15.26
Ru	1 dose vial x 10	$ 4.06	$ 7.53**	$ 8.88	$ 14.26
MR	1 dose vial x 10 10 dose vial	$ 6.55 $ 4.90	$ 11.32** -	$ 11.65 9.83	$ 19.55 -

*Includes Federal Excise Tax
**Prices through November 30, 1987

ATTACHMENT 9

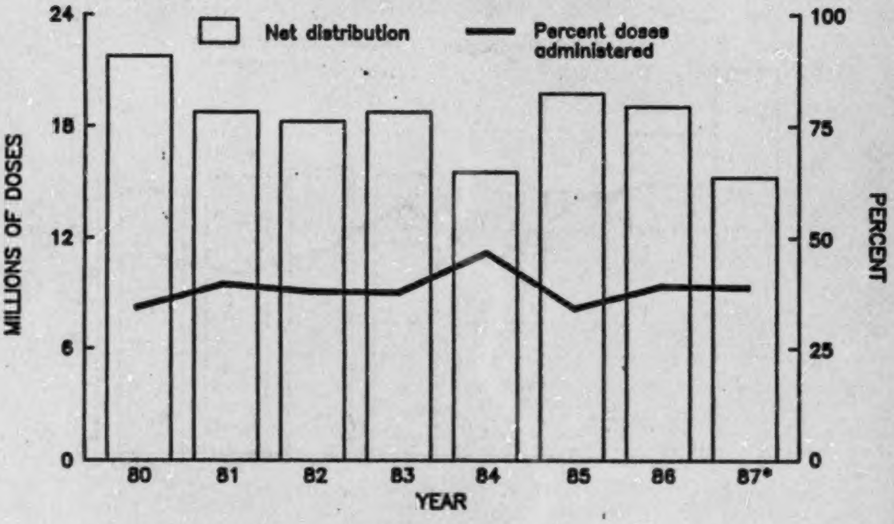
Status of CDC Vaccine Stockpile By End of FY 1988



18

ATTACHMENT 10

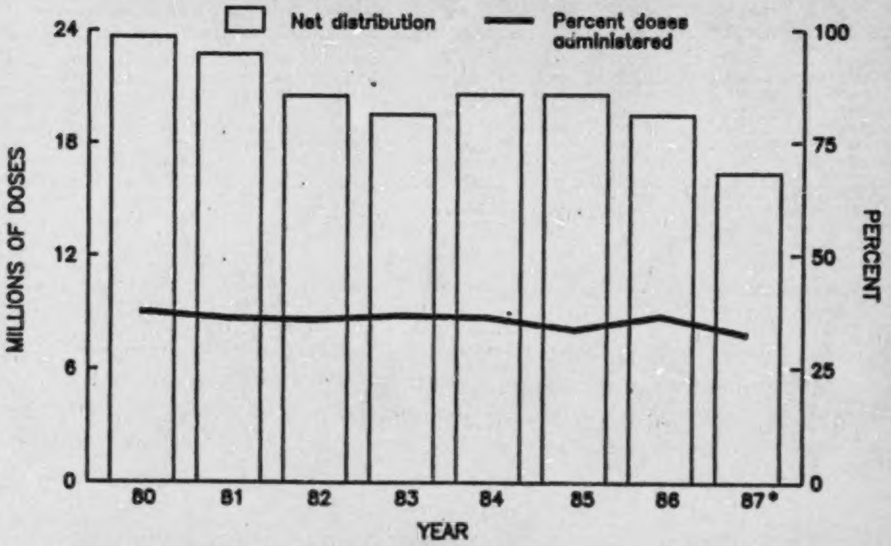
Net Distribution of DTP Vaccine and Percent Doses Administered in Public Sector in Relation to Net Distribution, United States, 1980–1987



* Represents 3/4 of the year, January–September.

ATTACHMENT 11

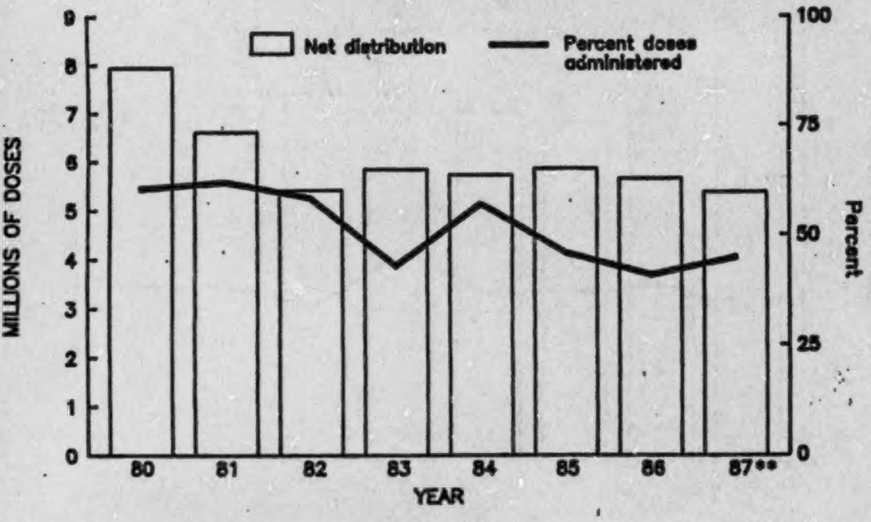
Net Distribution of OPV Vaccine and Percent Doses Administered in Public Sector in Relation to Net Distribution, United States, 1980–1987



* Represents 3/4 of the year, January–September.

ATTACHMENT 12

Net Distribution of Measles* Vaccine and Percent Doses Administered in Public Sector in Relation to Net Distribution, United States, 1980–1987



* All measles–containing products.
** Represents 3/4 of the year, January–September.

ATTACHMENT 13

Relative Relationship Between Doses Administered in Public Sector and Net Distribution of DTP, OPV, and Measles* 1980-1987

	DTP			OPV			Measles		
Year	Net Distribution	Doses Administered	%	Net Distributed	Doses Adminis-tered	%	Net Distributed (x1000)	Doses Administered (x1000)	%
1980	21,816	7,474	34.3	23,746	8,812	37.1	7,958	4,793	60.2
1981	18,827	7,483	39.7	22,785	8,125	35.7	6,625	4,085	61.7
1982	18,261	6,933	38.0	20,630	7,309	35.4	5,436	3,159	58.1
1983	18,793	7,104	37.8	19,590	7,103	36.3	5,859	2,505	42.8
1984	15,635	7,324	46.8	20,662	7,426	35.9	5,748	3,265	56.8
1985	19,786	6,773	34.2	20,704	6,901	33.3	5,882	2,689	45.7
1986	18,981	7,443	39.2	19,601	7,092	36.2	5,678	2,315	40.8
1987**	15,303	5,954	38.9	16,533	5,340	32.3	5,399	2,421	44.8

* All Measles containing products
** Represents 3/4 of the year, January-September.

Senator BUMPERS [presiding]. Dr. Mason, how do you account for the changes in mumps, as you look from 1977 to 1987? In 1977 we had about 21,500 cases of mumps, and then we started going through a very dramatic reduction and got down to 2,982 cases in 1985. It looks like we were on our way to eradicating mumps.

Then all of a sudden last year, we jumped to 12,300 cases. What accounted for that?

Dr. MASON. There are 16 States that do not require immunization for mumps; more than 64 percent of those cases occurred in 5 States where mumps immunization has not been required by comprehensive school law.

Dr. Hinman, do you want to elaborate on that?

Dr. HINMAN. I think that has been a very important factor. Also, it certainly is the case that from the moment of licensure of mumps vaccine in 1967 until the late 1970's it was not viewed as having the same priority as measles or rubella vaccine, and consequently there were many children who were protected against measles and rubella who did not get mumps vaccine.

The outbreaks that we saw last year were primarily in school aged children, junior high school and high school students who had never received mumps vaccine. Most of them had good documentation of having received measles and rubella vaccines.

So we are in fact seeing the result of incomplete introduction of the vaccine initially.

Senator BUMPERS. It is really interesting. We had an alarming increase in mumps last year, and yet the instance of rubella continued to decline to an all-time low last year.

Dr. HINMAN. That is correct.

Senator BUMPERS. And yet those shots are invariably given at the same time, are they not? The MMR vaccine is one shot?

Dr. HINMAN. It is now. About 90 percent or more of all mumps vaccine, for example, is given as MMR vaccine. But until the late 1970's, the vaccines were often given as separate antigens and we were not providing, for example, through the grant program a specific support for the single antigen mumps vaccine.

It has been since the eighties that we have been using almost exclusively MMR vaccine.

Senator BUMPERS. Dr. Mason, how do you account for the decline in the number of vaccine injury lawsuits filed from about 260 lawsuits in 1986 to 200 lawsuits in 1987?

Dr. HINMAN. Yes.

Senator BUMPERS. That is the chart I am referring to. Is that just by coincidence, or are manufacturers settling more lawsuits before they are brought to trial? What is the reason for this change?

Dr. MASON. I think Mr. Johnson will probably be able to shed light on that. Dr. Hinman, would you like to comment?

Dr. HINMAN. I think the manufacturers are certainly in a better position to respond. Our data really relates only to the numbers of claims filed and the number completed through whatever process, either through settlement or court decision.

The number settled is a minority of the cases that are filed. There has been a fair amount of speculation that the reason for the decline in 1987 relates in part to persons who might have otherwise filed a claim waiting to see what would happen with the compensation program, and that they may be applying to the compensation program rather than bringing suit.

Senator BUMPERS. You mentioned a moment ago that there are very low immunization levels in 20 counties in this Nation. Are those urban counties, are they rural counties, or is it a mix?

Dr. HINMAN. They are primarily urban counties and they represent major population centers. These counties contain something on the order of 15 or 16 percent of the population of the country, even though they represent only 20 out of 3,000 counties.

They include Miami, Los Angeles, New York City, Jersey City, these areas.

Senator BUMPERS. Well, is that because of the cost of vaccines, limited access to public health clinics, or because poverty is so pervasive?

Dr. HINMAN. There seems to be a variety of factors involved, ranging from the competing priorities for parents who are living on marginal economic benefits to the accessibility of services. But it is certainly the case, for example, that in recent years the preschool outbreaks of measles we have seen have been primarily in these areas.

Dr. MASON. These are areas that do not just have problems with immunization levels, but a whole series of health problems seem to be concentrated in these urban areas. We are dealing with poverty, as Dr. Hinman has said, with a lack of education, with social disadvantage. And there is often drug abuse and other problems.

And all of this makes delivery of health care services very, very difficult.

Senator BUMPERS. When you look at that same chart of lawsuits filed by parents on behalf of injured children, there is an incredible increase in the number of cases filed from 1981.

In 1979 there was apparently only one lawsuit filed. In 1980, how many were there?

Dr. HINMAN. I think there were two or three.

Senator BUMPERS. And two or three cases were brought in 1982. Then all of a sudden in 1983 the number of cases filed begins to increase, and they just shoot up until 1986 when 260 lawsuits were brought.

Is that because of that great television documentary that only showed one side of this question?

Dr. HINMAN. There has been an increase in the number of media stories about pertussis and pertussis vaccine, which in many ways parallels this curve in lawsuits. And I think there is a lot of speculation that the television program had a lot to do with people becoming aware that problems that they saw in their children might be related to vaccines, and thereby resulted in claims.

Senator BUMPERS. I believe it is the NBC affiliate here in Washington that first showed the documentary on pertussis vaccine, was it not? Or do you know?

Dr. HINMAN. That is correct.

Senator BUMPERS. I was very disturbed by that documentary. I could not believe that it showed a limited picture of the effects and benefits of the DTP immunization. Not one thing about the benefits of the pertussis vaccine, which the President of the American Academy of Pediatrics is going to testify to in a moment.

I thought that documentary was irresponsible, but I am not suggesting that is the only reason for the increase in the number of lawsuits that started at about that time.

I am simply saying they frightened parents into keeping their children away from the immunization program, and you and I both know that that does not serve the interests of this program, which as I have already pointed out has been so highly successful.

Now, let me ask you about these increases in the prices of vaccines and ask you if you think, for example, the MMR price increases implemented by Merck are justified, in view of the fact that we passed this vaccine compensation program?

Do you think there is any justification, Dr. Mason, for actually increasing the price while we are doing our very best to protect the manufacturers from vaccine injury lawsuits?

Dr. MASON. Senator Bumpers, we can only speculate on that, because we really do not have any data in terms of costs and things of that nature. We are concerned about those prices, and yet we really do not have any data on which to base any comments.

Senator BUMPERS. Well, of course, that is proprietary information. I do not expect Lederle or Merck or anybody else to share all those numbers with us. But it is very difficult for me to understand how they continue to say that manufacturing vaccines is almost a nonprofit item with them.

You know that is their allegation, that they make no money from manufacturing this vaccine?

Dr. HINMAN. I think that they have on occasion characterized the vaccine field in toto—some of the comments that have been made, for example, about pricing on MMR vaccine have related to the cost of development of other vaccines.

But I would not presume to speak for the manufacturer.

Senator BUMPERS. Well, even with the incidence of lawsuits, I cannot understand how DTP in the private sector could go up 3,000 percent in 6 years, and in the public sector by 6,000 percent. When you go from 15 cents—you think about this—15 cents a dose in 1982 to $9.62 in 1988, that is a 6,000-percent increase.

Dr. MASON. When we attempt to negotiate a contract, we wish that we had more than one bidder in some of those cases. I think it is very difficult when there is only one supplier of vaccine.

So whenever we are in that situation, of course, then we have difficulty in negotiating a price because we are more accustomed to a competitive marketplace, where those things at least can better be examined.

We are happy that with some of the other vaccines competition is in the marketplace, and we hope with the compensation law that additional vaccine manufacturers may be in one way or another brought into the field so that competition can occur.

Senator BUMPERS. I wanted to be sure that my notes were correct on this about Merck. And it is my understanding Merck has liability insurance. We can kick them around since they are not here. [Laughter.]

They do have liability insurance, and they are the only manufacturer of childhood vaccines that has increased the private and public sector prices for MMR and, also slapped on the entire Federal surcharge of over $4 for this particular vaccine.

I do not much blame them for declining to come today. I probably would have declined, too.

But let me ask you another question about funding. I do not feel that you have nearly a big enough request in your 1989 budget to cover the H-flu vaccine. As I understand it, the vaccine we have been using protects children 2 years and older against bacterial meningitis.

And a recently licensed H-flu vaccine can be given now at 18 months, so that we start protecting children at 18 months instead of 2 years. But the cost is going to be more, is that not true? Is the new vaccine not more expensive?

Dr. MASON. We anticipate that the cost of the new conjugate vaccine may be more expensive. Of course, we have not negotiated a contract yet and so we do not know for certain.

We are hopeful that, since there was a fairly good inflation level placed in anticipating the cost of the other vaccines, that as a result of these negotiations we may be able to save some money on the others, and that may in turn provide additional money in case we are faced with an increase in costs for the new H-flu vaccine. We hope it will all work out.

Senator BUMPERS. I have found around here, Dr. Mason, when you live on hope you get a lot of disappointments.

Dr. MASON. I think we are caught in the same issue. The budget reflects a decision within the Department as to where to put money to stay within the agreements of the summit. And these are basically monetary decisions.

Senator BUMPERS. You are also requesting a shift of $18 million in the State operations program to the vaccine program, which means you are going to use that $18 million that would otherwise go to the States for purchasing vaccines.

Was that a part of the budget summit agreement?

Dr. MASON. The summit agreement, as you know, was related to the amount that would be spent, not related to any particular aspect such as State operations. There is no question that I think Mr. Waxman compared it to an automobile without wheels. It is not enough to have vaccine. You have got to have the machinery to get it into the arms, to keep records, to store it, and to even promote its use.

We have been talking about the preschoolers and that takes an active process. And so these are tradeoffs, there is no question about it.

Senator BUMPERS. Who is going to make up the $18 million shortfall? Are the States going to make it up, or it is not going to be made up?

Dr. MASON. As it now exists, that will have to be made up out of State and local funds or it just will not be there.

Senator BUMPERS. You admit that we are well below the 6-month level of vaccine stockpile which has been a goal? Yet you request no funding in fiscal year 1989 for the vaccine stockpile.

Now, this is all apparently because of the increase in the cost of vaccines. It is just that in order to purchase the same number of doses in fiscal year 1989 as in fiscal year 1988, you have to eliminate funding for some parts of the program?

Now, that is a tradeoff. Is that tradeoff worth jeopardizing building that stockpile that we need if we happen to have an epidemic or an interruption in vaccine supplies?

Dr. MASON. You are absolutely right. In a way we are robbing Peter to pay Paul in this process. These are tradeoffs and decisions that have to be made.

I think that the Secretary and everyone else would wish that there was money that could be placed there for that purpose, but it was felt that there are other pressing issues, and the highest priority would be to maintain at least at a level state the number of doses that could be purchased with Federal funds.

Senator BUMPERS. Let me just ask you a couple of final questions.

What is the status of the new acellular pertussis vaccine? Is this a Japanese vaccine that is being tested in Sweden?

Dr. HINMAN. There are several candidate acellular pertussis vaccines. The Japanese have had the most experience with acellular vaccines.

Senator BUMPERS. Do they use it?

Dr. HINMAN. Yes; they have been using acellular pertussis vaccines routinely since 1981 in children beginning at 2 years of age, not in infancy.

We participated with the Public Health Service, with the Swedish Government and the World Health Organization in carrying out a very sizable field trial of two of the Japanese acellular pertussis vaccines in Sweden. This was just completed this past winter.

The results from that trial were mixed. The vaccines were found to be less associated with fever, with local reactions, and with convulsions than the current wholesale pertussis vaccines.

However, they were not as effective as had been hoped. They were effective on the order of 70 percent in preventing all culture-proven cases of pertussis and 80 percent in preventing more serious disease. These levels are probably somewhat lower than the effectiveness of the current whole cell vaccine. I say probably because they were not compared head to head in the trial.

We have recently sponsored a workshop at the National Institutes of Health to review the results of the Swedish acellular trial as well as other pertussis vaccine trials.

I wish I could say that we would have this year an acellular pertussis vaccine available for licensure. Lederle might wish to comment on this during their testimony, since they have among United States manufacturers, I think, taken the most active role in trying to evaluate and pursue approval of a Japanese acellular pertussis vaccine in this country.

Senator BUMPERS. Are we doing independent research on an improved vaccine in this area?

Dr. HINMAN. There is quite a lot of research going on, both internal——

Senator BUMPERS. In the private sector?

Dr. HINMAN. Both in the private sector and in the public sector. There is a candidate acellular vaccine that has been developed by Dr. John Robbins of the National Institute of Child Health and Human Development. There are vaccines under development, to my knowledge, at each of the current manufacturers of DTP vaccine. Lederle can speak to their own research. I know that other manufacturers are doing research on vaccines that they, themselves, are developing.

In addition, there are some foreign manufacturers, such as the Merieux Institute from France, which are interested in potentially approaching the United States market with an acellular vaccine.

Senator BUMPERS. When you said we found the results were mixed but you didn't find them as effective, do you mean effective in preventing the disease?

Dr. HINMAN. Yes.

Senator BUMPERS. Some people who were immunized actually got the disease?

Dr. HINMAN. That is correct. That is true with any vaccine.

Senator BUMPERS. Is that true of the present DTP shots?

Dr. HINMAN. Yes, it is.

Senator BUMPERS. Some people will get it?

Dr. HINMAN. That is correct.

Senator BUMPERS. What percentage?

Dr. HINMAN. Our recent estimates of efficacy of the whole cell pertussis vaccine in this country are on the order of 80 to 90 percent efficacy in preventing the disease.

Senator BUMPERS. When I was Governor of the State and Betty Bumpers was immunizing all the children in Arkansas, we had a statistic. They had a cartoon of children running everytime they saw her coming.

We had a figure back then that was, as I recall, 8 percent of the people who are institutionalized in this country, both children and adults, are there because of a syndrome from a preventable childhood disease.

Does that sound like a reasonable figure to you? That was in 1973, I believe, that I heard that.

Dr. HINMAN. That certainly would have been the case for persons institutionalized because of deafness. The rubella epidemic in 1964–65 resulted in a tremendous burden of children with severe congenital defects, particularly deafness.

You may recall that a couple of years ago there was a major problem with the Rochester Institute of Technology and Gallaudet University, which are the only two schools for the deaf in this country. Among this rubella cohort, the bulge appeared in these colleges. They really did not have the capacity to reach these people.

I think that this is less true now because of the impact of the vaccine.

Senator BUMPERS. Yes.

Finally, let me ask you this. Considering the cost of the vaccines today and the fact that the cost of vaccines in the private sector are so much more than they are in the public sector, how would you feel about the United States getting into the vaccine manufacturing business?

Somebody else here is going to testify about how they have used CDC as their purchasing agent. I think all States ought to be working toward that with your cooperation, Dr. Mason.

Dr. MASON. We have been asked that question a number of times, and for a number of reasons I think we would discourage movement in that direction. There are a number of reasons for that.

First of all, in our country we have always believed in a government/private sector relationship for the development of supplies.

Second, it would probably inhibit research in the private sector.

Third, it would require the acquisition on the part of government of capacity to do that.

Fourth, there could well be delays in passing the baton from the private sector to the public sector.

Finally, it would put us, as government, in the position of both producing and licensing and inspecting ourselves, which may represent some conflict of interest.

I would hope that there would be a way that we could work out the difficulties that we are having with immunizing our children without nationalizing, so to speak, our vaccine industry. There must be a better way than that, although there are other nations that have gone that route.

Senator BUMPERS. What if Merck, which is the only supplier of MMR vaccine, should abandon the field? What would you suggest?

Dr. MASON. There are two approaches that might be taken. One is to go all the way and take over vaccine production, buy them out so to speak, and nationalize production of MMR.

I would think there is a step short of that that would be better, and in that kind of a situation it would be better for us to just purchase whatever they manufactured and then indemnify them.

Senator BUMPERS. You mean assume all the liabilities?

Dr. MASON. Assume all the liabilities. I think that would be a step that I would take before I would go all the way to getting into public sector production.

Senator BUMPERS. Let me say, Dr. Mason, I agree with you on that. I am certainly not interested in the United States getting into the manufacturing business, but it is something you always have to think about simply because of the very limited number of people who are in it and, quite frankly, who are willing to be in it.

There are a lot of headaches with manufacturing these vaccines and taking all the lawsuits and risk involved in it, but I remember it has not been too many years ago when it looked like we were going to wind up in that posture. So I think we have to keep our powder dry on that issue.

I think all of the reasons you gave for us not getting into it are perfectly legitimate.

We will probably have some additional questions to submit to you for the record, but I thank both of you very much for being with us.

Dr. MASON. Thank you for the opportunity of appearing before you, and we would be happy to respond to any questions you might have.

Senator BUMPERS. Thank you.

STATEMENT OF ROBERT B. JOHNSON, PRESIDENT, LEDERLE LABORATORIES, AMERICAN CYANAMID CO.

ACCOMPANIED BY:

RONALD CRACUS, LEGAL DEPARTMENT
DR. RONALD SALDARINI, LEDERLE

Senator BUMPERS. Our next witness is Robert B. Johnson, president, Lederle Laboratories, Division of American Cyanamid.

Mr. JOHNSON. Mr. Chairman, I brought with me on my right Ronald Cracus, who is from our legal department, and on my left is Dr. Ronald Saldarini, who is responsible for our biological business at Lederle.

I am pleased to be here today to offer Lederle Laboratory's support for the increased funding for the two essential public health programs. I urge you to increase funds for the State Childhood Immunization Programs and to allow for the implementation of the National Childhood Vaccine Injury Act.

Lederle Laboratories, a Division of American Cyanamid Co., manufactures three of four major childhood vaccines: oral polio vaccine; the diphtheria tetanus pertussis vaccine; and haemophilus influenza vaccine. We currently supply these vaccines to the private sector and to the Federal Government.

As you are aware, approximately one-half of the childhood vaccines administered in this country are distributed through agencies of the Federal Government, primarily the Centers for Disease Control.

Lederle also supports an extensive research and development program for new vaccines. Major projects under active investigation include an acellular pertussis vaccine which may replace the current wholesale product and may be combined with our existing toxoid products, diphtheria and tetanus, plus an enhanced injectable polio vaccine using the Sabin strains.

Other research projects involve vaccines for herpes, AIDS, respiratory syncytial virus, and cytomegalovirus.

It is our understanding that this subcommittee is considering the need for increased appropriations to help supply needed childhood vaccines through State and local immunization programs. These programs represent one of the greatest successes in the public health field.

In order to maintain the high levels of immunization that this Nation has achieved, we need both the committed support of the private medical community and the assistance of public programs designed to reach low income segments of the population.

To maintain immunization levels, it is important that appropriations keep pace with the total cost of vaccine distributed through the public sector. Our field reports indicate that because of liability concerns, many physicians are referring patients to public clinics for their immunization.

Lederle has reduced its DTP vaccine price twice within the last 10 months even though the overall cost per dose to the Government has increased. The reason for this increase is that effective January 1, 1988, the price of DTP vaccine includes a mandated Federal excise tax of $4.56 per dose.

The cost of oral polio vaccine did not go up because Lederle absorbed the Federal excise tax.

If appropriations do not increase to cover these new taxes, State and local health departments will either have to cut back on their vaccination programs or find new sources of funding. Many States will have difficulty finding needed funds to offset the new Federal State. In order to maintain essential high immunization levels across the Nation, strong Federal support for these State and local programs is necessary.

The second aspect of the vaccination program is also before this subcommittee. The vaccine compensation amendments of 1987 authorize an appropriation of $80 million in fiscal year 1989 to fund the National Childhood Vaccine Injury Act. These funds were designed to provide compensation for vaccine-related injuries associated with the administration of vaccines prior to October 1, 1988.

Lederle Laboratories has long supported the aim of providing fair compensation to persons injured in connection with the administration of vaccines. Although the specific legislation we favored would not have required Federal funding for a compensation system, Congress chose to enact a program that is to be funded in part by the new Federal excise tax on vaccines and, in part, by appropriations.

While we had differences over how implementation of the 1986 act should be accomplished, we now support the provision of adequate funds to carry out the intentions of the program. We hope that you will agree that these children and their families should now receive the compensation that Congress intended.

The law as enacted by Congress was designed to provide compensation while retaining the tort system. With regard to cases involving vaccines administered prior to October 1, 1988, claimants have their choice of seeking Federal compensation or pursuing tort remedies. Those who only seek Federal compensation receive compensation for future unreimbursable medical expenses, death benefits, and up to $30,000 for pain and suffering, lost earnings and attorneys fees.

To obtain this compensation, claimants need not prove fault. Instead, they only have to show that their symptoms fall within a vaccine injury table included in the legislation.

Congress obviously felt that this amount of compensation would help those individuals who could not win a tort suit. For example, some will have already filed lawsuits, while others will have decided that they have no significant chance of winning. Still others may prefer to avoid the difficulties associated with litigation, a point of view I can certainly understand.

Those who feel they can receive full compensation for their alleged damages by pursuing their rights in court will no doubt continue to do so. The funds being sought will do little to relieve the pressure of this kind of litigation. We have hundreds of suits now pending against us, and we fully expect that most of these cases will remain within the tort system; but funding the new compensation program will provide a useful alternative for those who might otherwise receive no assistance.

Subcommittee action on both of these needed appropriations will help to preserve and strengthen our Nation's childhood immunization program and provide fair compensation to those persons who have injuries caused by the rare side effects associated with the vaccines.

PREPARED STATEMENT

I would be happy to answer any questions that you may have, sir.

[The statement follows:]

STATEMENT OF ROBERT B. JOHNSON

I am pleased to be here today to offer Lederle Laboratories support for increased funding for an essential public health program. I urge you to increase funds for state childhood immunization programs and to allow for the implementation of the National Childhood Vaccine Injury Act.

We support increased appropriations during Fiscal Year 1989 for critical elements of the nation's childhood immunization programs.

Lederle Laboratories, a division of American Cyanamid Company, manufactures three of the four major childhood vaccines: oral polio vaccine, the diphtheria-tetanus-pertussis vaccine, and haemophilus influenzae vaccine. We currently supply these vaccines to the private sector and the federal government. As you are aware, approximately half of the childhood vaccines administered in this country are distributed through agencies of the federal government, primarily the Centers for Disease Control.

Lederle also supports an extensive research and development program for new vaccines. Major projects under active investigation include a new acellular pertussis vaccine which may replace the current whole cell product and be combined with our existing toxoid products, diphtheria and tetanus, plus vaccines for herpes, AIDS, respiratory syncytial virus (RSV) and cytomegalovirus (CMV).

RSV, a major cause of pneumonia and other respiratory illness in children and CMV, which is responsible for many congenital defects, are diseases whose incidence in infants have increased in the past several years. In conducting our R&D programs, Lederle works closely with academic institutions as well as several agencies of the Public Health Service.

It is our understanding that the Subcommittee is considering the need for increased appropriations to help supply needed childhood vaccines through state and local immunization programs.

These programs represent one of the greatest successes in the public health field. In order to maintain the high levels of immunization that this nation has achieved, we need both the committed support of the private medical community and the assistance of public programs designed to reach low-income segments of the population.

To maintain immunization levels, it is important that appropriations keep pace with the total cost of vaccines distributed through the public sector. Unfortunately, our field reports indicate that because of liability concerns, many physicians are referring patients to public clinics for their immunizations.

Lederle has reduced its DTP vaccine price twice within the past ten months, even though the overall cost per dose to the government has increased. The reason is effective January 1, 1988, the price of DTP vaccine includes the mandated federal excise tax of $4.56 per dose. Lederle did not pass on the $0.29 per dose tax on oral polio vaccine.

If appropriations do not increase to cover these new taxes, state and local health departments will either have to cut back on their vaccination programs or find new sources of funding. Many states will have difficulty finding needed funds to offset the new federal tax. In order to maintain essential high immunization levels across the nation, strong federal support for these state and local programs is necessary.

A second aspect of the vaccination program also is before this Subcommittee. The Vaccine Compensation Amendments of 1987 authorized appropriation of $80 million in Fiscal Year 1989 to fund the National Childhood Vaccine Injury Act. These funds were designed to provide compensation for vaccine-related injuries associated with the administration of vaccines prior to October 1, 1988.

Lederle Laboratories has long supported the aim of providing fair compensation to persons injured in connection with the administration of vaccines. Although the specific legislation we favored would not have required federal funding for a compensation system, Congress chose to enact a program that allows the U.S. Claims Court to award compensation to persons who meet the standards set forth in the Act. This compensation is to be funded in part by the new federal excise tax on vaccines and in part by appropriations.

While we had differences over how implementation of the 1986 Act should be accomplished, we are now united in our support of providing adequate funds to carry out the intentions of the program. We hope that you will agree that these children and their families should now receive the compensation that Congress intended.

The law as enacted by Congress was designed to provide compensation while retaining the tort system. With regard to cases involving vaccines administered prior to October 1, 1988, claimants have their choice of seeking federal compensation or pursuing tort remedies. Those who only seek federal compensation receive compensation for future unreimbursable medical expenses, death benefits, and up to $30,000 for pain and suffering, lost earnings, and attorneys fees. To obtain this compensation, claimants need not prove fault; instead, they only have to show that their symptoms fall within a vaccine-injury table included in the legislation.

Congress obviously felt that this amount of compensation would help those individuals who could not win a tort suit. For example, some will already have lost suits, while others will have decided that they have no significant chance of winning. Still others may prefer to avoid the difficulties associated with litigation--a point of view I can certainly understand.

Those who feel they can receive full compensation for their alleged damages by pursuing their rights in court will no doubt continue to do so. The funds being sought will do little to relieve the pressure of this kind of litigation. We have hundreds of suits now pending against us, and we fully expect most of those cases to remain within the tort system. But funding the new compensation program will provide a useful alternative for those who might otherwise receive no assistance.

Subcommittee action on both these needed appropriations will help preserve and strengthen our nation's childhood immunization program and provide fair compensation to those few persons who have injuries caused by rare side effects associated with the vaccines.

I would be happy to answer any questions you may have.

Senator BUMPERS. Thank you very much, Mr. Johnson. Let me just ask you a few preliminary questions.

Is your assumption right now that one-half of the people who have claims against Lederle will reject what is offered through the vaccine compensation system and one-half of them will accept, so that you are still going to be subjected to about 50 percent as many lawsuits as you are right now?

Mr. JOHNSON. Sir, I would like to clarify. You said those who currently have claims against Lederle.

Senator BUMPERS. Let us make this prospective, because the compensation vaccine program will cover past injuries only if we appropriate funds for compensation of past cases. So let us just talk about the prospective part of it.

Mr. JOHNSON. We believe, based on the number of lawsuits that are currently being filed, and we have reduced, as I indicated, our surcharge because of this reduction, but for the future outlook we would anticipate that there will still be a number of suits that will go through to the tort system. That number is what we have based our current internal liability surcharge on.

Senator BUMPERS. Would your assumption change dramatically if we made the maximum amount of recovery for pain and suffering $500,000 instead of $250,000?

Mr. JOHNSON. I do not believe that the limit on pain and suffering alone would be sufficient to make a dramatic change, since there are other compensatory factors that come into play, particularly when it goes through the tort system.

Senator BUMPERS. I do not want to be accused of that which I have accused the DPT documentary producers of doing but I do want to make this point. I not only am a former trial lawyer, but I am also still a parent.

As I prepared for this hearing and I thought about this whole question of the vaccine compensation bill, I wondered what I would do if I had a 1-year-old child who had a severe neurological reaction to this vaccine and who, for example, was going to have to be tended on a 24-

hour-a-day basis for the rest of his or her life. If I were in that situation, $250,000 would not seem like much.

$250,000 seems like nothing to me both as a trial lawyer and as a parent.

Mr. JOHNSON. I agree, sir, that $250,000 would certainly not compensate in any way for a child that has the damages that you indicate.

Senator BUMPERS. Let me interrupt you for the benefit of the record so that everybody will understand. There is a lot more in the compensation bill than just that. You get all your past and future medical expenses, and it can be a staggering amount of money.

But I am just talking about the pure cost of pain and suffering to the child. Of course, there is nothing in the vaccine compensation bill for mental anguish of the parents who have lost a perfectly healthy child.

I am sorry I interrupted you. Go ahead. I am just saying I would be hardpressed to accept $250,000 for pain and suffering. Would you?

Mr. JOHNSON. As a parent and a grandparent, I do not believe there is any compensation that can make up for that.

Senator BUMPERS. You cannot put a dollar value on it, of course. I can remember the time a few years ago when I was a trial lawyer when $250,000 would have looked like the Chase-Manhattan Bank to me, but today it is just not all that much money.

So let me ask you this. How many lawsuits filed or how many claims made against your company do you consider to be specious? I am not talking about nuisance lawsuits but claims which are suspect and maybe damages that were not even caused by the vaccine.

Mr. JOHNSON. Senator, as you know, the relationship between causation of the neurological problems that children experience and the administration of the vaccine is a subject that has been debated in scientific circles for some period of time.

As to the number that are specious claims, I cannot address that. Maybe Mr. Cracus can speak to that.

Senator BUMPERS. Would you care to comment on that?

Mr. CRACUS. That would be a very hard question to answer.

Senator BUMPERS. Would you pull that microphone up a little closer, please?

Mr. CRACUS. Certainly, Senator.

That would be a very difficult question to answer because of the absence of any proven scientific connection between the vaccine and the injuries that are alleged.

I can say, though, that a very large number of the claims assert injuries that almost all responsible authorities believe are not related to the vaccine at all.

Senator BUMPERS. I am not going to badger you for proprietary information or make you, as we lawyers, say, make admissions against interest, but you said in your testimony, Mr. Johnson, you have hundreds of lawsuits pending against Lederle.

Is that a correct statement? You have hundreds? Is that the low hundreds or the high hundreds?

Mr. JOHNSON. The last number of total suits that are currently pending is 245.

Senator BUMPERS. In 1987 you think the number of suits were down slightly from 1986?

Mr. JOHNSON. Yes, sir; they were down to about 70 during the year 1987.

Senator BUMPERS. That is about a 30 percent drop, is it not?

Mr. JOHNSON. Yes, sir; it is a drop. I am encouraged by that, but I am really holding back until we see where the trend is going.

Senator BUMPERS. You have no explanation for that drop?

Mr. JOHNSON. No, sir; not directly.

Senator BUMPERS. How many cases are you able to settle without a lawsuit, what percentage? 50 percent?

Mr. JOHNSON. I would hesitate to answer. Probably 25 percent or so of those cases that are valid.

Senator BUMPERS. Can you tell me based on your experience, since it is difficult to nail this down because Merck makes all the MMR, and I think that Lederle probably makes 60 to 65, maybe 70 percent of the DTP's; is that right?

Mr. JOHNSON. Depending on the point in time, yes, sir.

Senator BUMPERS. Based on your experience and assuming that roughly 40 to 50 percent of all the vaccine injury claims filed are filed against Lederle, do you think we are collecting an adequate tax to finance compensation for injured parties?

Mr. JOHNSON. I would believe that the number of cases that go through the compensation system that this $80 million would be applied toward, it may be enough. The reason I am hesitant is only because not knowing how the awards will be administered from the claims court, I think it is only going to be determined by experience.

I think the number was set in the bill based on the information that they had, that they felt that it would be adequate.

Senator BUMPERS. One thing that is confusing to me now is that CDC says that it is their best guess that 62 children suffer a severe neurological reaction to a DTP shot annually, roughly 1 out of every 310,000 DTP shots.

Now, last year Lederle alone had 70 lawsuits filed and the year before that 110. So there is a difference, certainly between the kinds of lawsuits that are being filed.

You are getting a lot of lawsuits that are less than a severe neurological reaction. Is that right?

Mr. JOHNSON. Yes, sir; we get that, plus you should also know that the suits that are filed in many cases will go back several years. So you almost have to take the year that the shot was administered, and although the suit may be filed this year it may well be for a vaccine that was given in 1972, for instance.

So that I do not think you can take directly those shots administered each year.

Senator BUMPERS. Let me ask you this question. We are now getting down to the meat of the coconut.

In 1985 Lederle imposed its own internal liability surcharge of $8 per dose; is that correct?

Mr. JOHNSON. It was in 1986, Senator.

Senator BUMPERS. Was it 1986?

Mr. JOHNSON. May 20, 1986, I believe.

Senator BUMPERS. OK, on May 20, 1986 you imposed an $8 internal surcharge.

Did you segregate that amount in some particular fund so that it is identifiable?

Mr. JOHNSON. Yes, sir; it is identifiable as a nonfunded reserve in the corporation's books.

Senator BUMPERS. How many doses did you manufacture then in 1986 after you imposed that surcharge?

Mr. JOHNSON. I do not remember a specific number, but it was probably in the range of 6 to 7 million.

Senator BUMPERS. As W. C. Fields used to say, "that ain't beanbag, is it?"

Mr. JOHNSON. No, sir.

Senator BUMPERS. Now, 6 million doses times $8 is roughly $48 million.

Apparently you concluded at some time that year or in 1987 that that was going to be more than enough to take care of the problem, because you reduced the surcharge from $8 to $5.25 a dose; correct?

Mr. JOHNSON. Yes; we reduced it, but based on what our experience, what we anticipated for future cases.

Senator BUMPERS. My assumption is correct, is it not, that you decided that $8 was going to be more than enough to take care of your future problem?

Mr. JOHNSON. I am not trying to dance with you on words, but because we are always looking forward as to the amounts that we will need for shots that are administered today into the future, this is where we made our adjustment, yes, sir.

Senator BUMPERS. The same thing you were saying a while ago. A shot that you give this year may not result in a lawsuit for 2, 3, 4 years down the pike.

Mr. JOHNSON. Correct.

Senator BUMPERS. Of course, some laws say that the parents cannot waive the statute of limitations for a child, that nobody can do that, and that child can bring a lawsuit after he attains majority, which is a really big problem for you as I understand it.

Mr. JOHNSON. Yes, sir.

Senator BUMPERS. As I say, we brought you here to help enlighten us about what we can anticipate both with the vaccine compensation injury bill and also these appropriations for adequate vaccines. I do not want us to run out of funds.

This year, on January 1 you further reduced your own internal surcharge by $1.93. Is that right?

Mr. JOHNSON. $2.62.

Senator BUMPERS. I am sorry. I got that wrong. You have reduced it by $2.63, which is one-half of the $5.25 you were charging. So you have further reduced it by 50 percent to $2.62.

Mr. JOHNSON. Yes, sir.

Senator BUMPERS. Now, my problem with that is this. While I applaud you for that, you also then began collecting the Federal surcharge of $4.56 on top of that, which makes a total surcharge of $7.20; is that correct?

Mr. JOHNSON. $7.18, yes, sir.

Senator BUMPERS. So you are actually collecting more now, almost as much as you did when you had your $8 surcharge, a figure you said you had concluded was more than enough.

Mr. JOHNSON. But recognizing that the $4.56 does not go into my reserve but is paid to the Federal Government; that the $2.62 is what is going into my reserve for those cases that will go through the tort system in the future.

Senator BUMPERS. That is the right answer, Mr. Johnson. I commend you for saying that. Obviously that is the right answer for Lederle.

But from our standpoint, we have gone through agony for several years here. I have not gone home more than at least once a month when my wife would confront me when I walked in, with the question "What are you doing about that vaccine compensation bill?"

The truth is we could not get it passed. When we did finally get it passed in 1986, we could not get it funded.

We felt that we were approving this system to encourage the very limited number of manufacturers to stay in the business because, as I pointed out a while ago, the Goverment has no business in the manufacturing business. We do not ever want to have to get into it, but we are at the mercy of the manufacturers. If you quit, we are in deep trouble.

Yet, we want to make sure that the consumer and the taxpayers who pick up the tab for a lot of this vaccine are being fairly treated.

Go ahead.

Mr. JOHNSON. I would like to point out to you that, as we have already done based on what our experience is, we have in fact reduced our surcharge. As you know, in the State of North Carolina, they have passed a vaccine compensation bill of their own, and we do not charge an internal surcharge in the State of North Carolina. We only collect the Federal excise tax, which we are required to do by law.

Senator BUMPERS. State that again. Why do you not charge that in North Carolina?

Mr. JOHNSON. Because they have a vaccine compensation bill that we believe provides adequate protection for us, and there is no need for us to then have an internal surcharge for those vials of DTP vaccine that are sold in the State of North Carolina.

Senator BUMPERS. What is the maximum amount North Carolina provides for an injured child?

Mr. JOHNSON. There is not a maximum, because they indicate that they will provide specific medical care; but up then beyond the medical care needs, a maximum of $300,000.

Senator BUMPERS. That does not sound as generous as our bill. It is a $300,000 total?

Mr. JOHNSON. $300,000 over and above their medical, educational and certain specified expenses that it does cover.

Senator BUMPERS. Now, do I understand you to say that they provide $300,000 plus all the medical expenses and so on?

Mr. JOHNSON. Yes, sir.

Senator BUMPERS. We provide $250,000. Are you saying that that $50,000 more that they provide than we do would warrant not charging any internal surcharge?

Mr. JOHNSON. But there are other factors besides just the limitation. They do have a limitation that if they go to tort, there again the same limits are imposed, whether they take compensation before or after tort.

So there is a maximum as far as what can be compensated for. That is where the major difference is. Under the Federal bill, since tort is still open as an option, then that is the unknown area that we are trying to protect against.

Senator BUMPERS. Now, Mr. Johnson, I understand your position on this. The thing that concerns me is now, with the collection of your internal surcharge of $2.62 plus the Federal surcharge which you collect for us of $4.56, those two combined represent $1.93 more than you were collecting before when you were out there all alone.

It is strange to me that the consumer is going to wind up paying $2 more for vaccine than they have been in the past.

Mr. JOHNSON. Because besides the excise tax, we still have the open tort question, and that is where we feel, based on experience and until we have experience otherwise, we can only make what our best guess for those future awards may be.

I think we have demonstrated in the past that where that experience permits us to reduce the price, we will do so. We are the only manufacturer that indicates on DTP, which has the major charges on our invoice, what those liability charges are.

So I think we have tried to be open about it so that at least the procurers of the vaccine, the purchasers of the vaccine, know where we are coming from.

Senator BUMPERS. You do not have enough in that fund already to justify reducing that or eliminating it?

Mr. JOHNSON. Sir, for every shot that is administered, we feel there is a degree of exposure. and that is how we base our $2.62 current internal surcharge.

So it is not a case of accumulating so much and hoping that is enough. It is that every shot that is administered you must in fact provide for.

Senator BUMPERS. Is it Lederle's contention that you do not make any money off this vaccine?

Mr. JOHNSON. Off of DTP?

Senator BUMPERS. Yes.

Mr. JOHNSON. We price DTP so that it is basically a break-even situation. That will depend on what the total volume of the vaccine is that is produced each year.

Senator BUMPERS. Would you like to see the compensation vaccine program made an exclusive remedy?

Mr. JOHNSON. Exclusive remedy would certainly provide a known entity against which we could work and would probably reduce the surcharge. I would have to look at the details of what it provides.

Senator BUMPERS. Staff just handed me a note that I found interesting; that is, North Carolina deems any injured child to be eligible for MCH and Medicaid. So Uncle Sugar is picking up a good part of the tab. That is really interesting to me.

Mr. Johnson, you have been a fine witness, and it has been helpful to me. I appreciate very much all of you coming here this afternoon to share this with us, which is more than your competitors were willing to do. We really appreciate it.

Thank you.

STATEMENTS OF:

GERRI COHN, DISSATISFIED PARENTS TOGETHER

DR. RICHARD M. NARKEWICZ, PRESIDENT, AMERICAN ACADEMY OF PEDIATRICS

DR. ROBERTA COFFIN, COMMISSIONER, VERMONT DEPARTMENT OF HEALTH

KAY JOHNSON, SENIOR HEALTH SPECIALIST, CHILDREN'S DEFENSE FUND

Senator BUMPERS. Our next witness is a panel consisting of Gerri Cohn, Dissatisfied Parents Together; Dr. Richard Narkewicz, President, American Academy of Pediatrics; Dr. Roberta Coffin, Commissioner of Vermont, Department of Health; and Kay Johnson, Senior Health Specialist with the Children's Defense Fund.

I do not want to cut anybody off and we will try to have a discussion, but if you will summarize it will give us more time for questions and a discussion.

Gerri Cohn, Dissatisfied Parents, you are No. 1 on my list, so please proceed.

Ms. COHN. Good afternoon. On behalf of Dissatisfied Parents Together [DPT], I want to express our appreciation for the hearing which is being held today and for the opportunity to testify.

My name is Gerri Cohn, and I am president of Dissatisfied Parents Together. Dissatisfied Parents Together is a nationwide group of families whose children have died or suffered brain injury or other severe handicaps as a reaction to legally mandated childhood vaccines.

For more than 5 years now, our group has pushed for safer vaccines, for better information on the dangers as well as the benefits of childhood vaccines, for more parental freedom of choice, and for an adequate compensation program to care for our children who suffer long-term disabling vaccine reactions.

In 1986 part of our program became law. In 1987 a tax was enacted to fund the compensation program for children who are injured by these legally mandate vaccines in the future; but unless this subcommittee acts, there will be no compensation program for the families whose children have been injured or died in the past. Their only alternative will remain a lawsuit against the vaccine manufacturers and/or the doctors.

Our plea and our message to this subcommittee is simple: Please provide the full appropriation which Congress has authorized to carry out the compensation program for these children which Congress has twice enacted into law.

The need is great. Our children suffer multiple handicaps and often require round-the-clock care, special education, and expensive medical attention. Our cause is just and unique. No other group of children in this Nation have been forced by law to take products for the good of the many which are known to cause severe disability, even death, for some.

Our request is modest. Only future unreimbursed medical expenses plus a limited amount for pain and suffering, lost earnings, and attorneys fees are provided for those children who receive compensation, which will be a $30,000 maximum.

Thus, we join with the vaccine manufacturers, Merck, Lederle, Connaught, and American Home Products, the American Academy of Pediatrics and State health officials in urging full appropriation for this program.

In addition, we support increased appropriations to permit childhood vaccines to be made available to all who want them at an affordable price.

We strongly support the parents' right to say no, but we also support the availability of vaccines for all parents who want these vaccines for their children.

Finally, we urge this subcommittee to provide earmarked funding to support the new laws mandate to the Health and Human Services Department for research and licensing of safer vaccine.

The recent HHS symposium on acellular pertussis vaccine trials in Sweden makes one thing clear: Safer and at least equally effecting whooping cough vaccines are now available. The present U.S. whooping cough vaccine is long overdue for retirement and substitution with a safer, more technologically up-to-date product.

This subcommittee can protect our children, make the immunization program more credible and cost effective, and save money and lives in the process by authorizing the authorized funds for a safer vaccine program.

PREPARED STATEMENT

We appreciate this opportunity to appear today. We applaud the leadership of Senators Kennedy, Hatch, Bumpers, and Metzenbaum and Congressman Henry Waxman in getting two-thirds of the legislative job done. Now we ask for your help in taking the legislative action that our children deserve.

Thank you.

[The statement follows:]

STATEMENT OF GERRIE COHN

Good afternoon. On behalf of Dissatisfied Parents Together [DPT], I want to express our appreciation for the hearing which is being held today and for the opportunity to testify. My name is Gerrie Cohn and I am the president of Dissatisfied Parents Together.

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Senator BUMPERS. Thank you.

Dr. Narkewicz.

Ms. COHN. Excuse me. I have a disabled daughter and need to pick her up. May I be excused?

Senator BUMPERS. Certainly.

Ms. COHN. Thank you.

Ms. JOHNSON. Senator Bumpers, we have decided that we could present you the most clear amount of testimony if we begin with me and then move down the line to my right.

Senator BUMPERS. That is quite all right.

STATEMENT OF KAY JOHNSON

Ms. JOHNSON. My name is Kay Johnson. Senator Bumpers, I am pleased to have this opportunity to appear before you today on behalf of the Children's Defense Fund.

In the past few years we have become increasingly concerned about the immunization status of American children, and we know that the immunization rates for American children are stagnating over all and even declining in some crucial age groups.

We feel that at a time when UNICEF and Third World nations are conducting a worldwide campaign to immunize children against preventable diseases, U.S. leadership must not fail our children. We view this hearing as a further hearing as a further indication of your concern and another positive step toward reversing our course.

We know that to protect public health, a high level of immunization throughout the population must be achieved and maintained to prevent outbreaks of vaccine-preventable disease and that a high immunization penetration rate plays two roles: First, the crucial method of protecting persons, particularly infants and young children, who are not yet fully immunized; and second, a consistently high penetration rate ultimately can lead to the complete eradication of a disease.

Thus, the system for childhood immunization is crucial both for the prevention of infectious disease among individuals and on a communitywide basis, and the failure of this system can lead to disease outbreak.

Recent statistics from the Centers for Disease Control indicate that cracks may have developed in our childhood immunization system, and my written testimony reviews the Nation's progress toward meeting the Surgeon General's 1990 objectives for the Nation, for increasing childhood immunization, and for reducing the incidence of certain diseases. It also examines the adequacy of public immunization funding levels and Federal immunization monitoring and surveillance activities.

I would like to summarize that testimony briefly and include my full statement in the record, and then talk just a moment about what we have recommended.

First, we know that childhood immunization rates appear to be falling for our youngest children and that for our 2 year olds, the Nation is moving away from the Surgeon General's objectives for the improvement of services for preschool aged children.

I stress to you that no data collection system we have in this country is perfect. I work a lot with vital statistics, which are of course far more perfect than our survey system, but that we use these as the only indicators that we have for telling us which direction our Nation is moving in in terms of progress.

We know that when we look at the period between 1980 and 1985, the Nation is moving in the wrong direction in each disease category for our 2 year olds and that we are not moving toward that goal of having 90 percent of all of our 2 year olds fully immunized by the year 1990.

Second, we know that childhood immunization rates for specific diseases are particularly problematic. For example, we know that by 1985 nearly 1 in 10 nonwhite children had received no dose of polio, and 39 percent of nonwhite children ages 1 to 4 were not fully immunized.

We also know that for infants the problem is severe. To be adequately immunized against polio, infants should receive a dose of polio vaccine at 2 months and another at 4 months. Yet, by 1985 20 percent of all infants and 40 percent of nonwhite infants had not received the recommended two doses of polio vaccines.

In the case of DPT, we know that despite great fears raised over the protective vaccine's deleterious side effects in a very few infants, the percentage of children ages 1 to 4 with no reported dosages rose only from 0.7 to 0.8 percent. At the same time, the number of children younger than age 1 not immunized against DTP climbed by over 10 percent, while the percentage of nonwhite infants not fully immunized climbed by 68 percent. Many of those infants had received one dose and were not able to go back and be fully immunized.

We know that immunization levels in the Nation's largest cities generally are depressed and that low mumps immunization levels in urban areas exemplify this problem.

In 1985 in the Nation's largest cities, 26 percent of all children and 35 percent of nonwhite children ages 1 to 4 years had received no dose of mumps vaccine.

We also know that certain disease rates are increasing. At current rates, the United States will not meet the Surgeon General's objectives for the reduction of disease rates for measles, for mumps, and for pertussis.

For example, after dropping to a low point of about 1,500 cases in 1983, nearly 6,300 measles cases were reported in 1986. The Centers for Disease Control has found that 83 percent of reported measles cases among children 16 months to 4 years in that year were preventable through immunization.

Furthermore, in 1986, after 15 years of almost continuous decline in the reported incidence of mumps, a nationwide increase in cases of mumps was reported. The CDC shows a more than doubling of mumps incidence, from 2,982 in 1975 to 7,790 cases in 1986.

The CDC's statistics suggest that the recent increases largely have been a result of illness among unvaccinated teens; however, even among infants the reported number of cases grew from 29 cases in 1985 to 142 cases in 1986. The problem is not isolated alone among teenagers.

It is also of great concern that the reported cases of pertussis more than tripled between 1981 and 1986, reaching 4,195, the highest reported number since 1970. Rates of pertussis were particularly high among infants, and we know that the consequences of pertussis can be very serious among infants.

I would like to conclude by saying that there has been a substantial increase in the United States in the rates of measles and a resurgence in cases of mumps and pertussis; that immunization rates for our youngest children have leveled off and declined. If recent trends continue, the Nation will fail to meet about one-half the Surgeon General's 1990 objectives for the Nation in the area of immunization.

To insure greater success, the Children's Defense Fund recommends the following:

First, appropriation of sufficient funds in the immunization program to enable the CDC to make vaccines available to all children. Data from the first half of this decade suggests that more doses are needed if we are to fully immunize all children.

CDF recommends the appropriation of an additional $40 million for the grants program in fiscal year 1989; however, greater amounts may be needed if the vaccine costs include the newly applied excise taxes.

Second, funds appropriated for fiscal year 1989 should allow the Centers for Disease Control to continue support for the national immunization system and not just for the purchase of vaccines. Direct service delivery is only one important component of our national system.

At the funding level proposed for fiscal year 1989, $18 million would have to be cut out of central administrative support to allow the CDC to maintain the number of doses of vaccine. Because these activities both support the States and insure that we have a national system to prevent childhood disease, it must be continued and supported.

Third, a continued commitment to maintenance of the vaccine stockpile is essential. Appropriations levels for the vaccine stockpile should be sufficient to allow for at least a 6-month supply of vaccine.

Fourth, the Medicaid Infant Mortality Amendments of 1988 should be enacted immediately. These bills would extend Medicaid coverage to all poor infants in fiscal year 1989. An enactment of these provisions could insure the financing for immunization for tens of thousands of low income children.

Fifth, restoration of the immunization surveillance system or replacement of the prior system with a new annual immunization survey. Given certain adverse trends in immunization status and recent outbreaks of disease across the Nation, abandoning this system is a serious mistake in public health terms.

Senator, I do not believe that this Nation cannot design a system to survey the Nation about its health and its immunization status.

Sixth, appropriation of sufficient funds to provide fair compensation for families with children suffering from injuries related to vaccines administered before October 1988. These funds are urgently needed and should be made available at the soonest possible opportunity.

Finally, we believe that Congress and the U.S. Department of Health and Human Services should begin now to adopt policies which can insure an adequate system for providing childhood immunizations by 1992.

Meeting the Surgeon General's objectives even by that year will require a commitment such as was made in the late 1970's. That would include continued increases in funding levels for key child health programs to compensate for the vaccine price inflation.

It would include aggressive efforts to improve and sustain immunization levels.

It would include studies of disease outbreaks and their causes, public education campaigns regarding the importance of childhood immunization, and, of course, ongoing surveillance of a detailed nature.

The U.S. Office of Technology Assessment has recently released a landmark report entitled "Healthy Children: Investing in the Future." In that report, they concluded that the cost effectiveness of childhood vaccines is well established. We have all heard that today and before.

OTA has reported that such vaccines have been found not only to be of medical benefit but also to be cost saving.

At the same time, that report documents our failure to immunize our younger children with immunization levels for American infants significantly lower than several other industrialized countries.

It also documents the considerable differences in immunization status which persist with respect to race and geographic location.

PREPARED STATEMENT

We believe that the Nation cannot afford preventable illness, disability or death among our children and that we must act now to insure that all children have access to affordable, safe vaccines and recommit ourselves to the goal of disease eradication wherever possible.

Thank you.

[The statement follows:]

STATEMENT OF KAY JOHNSON

Mr. Chairman and members of the Subcommittee, I am pleased to have this opportunity to appear before you today on behalf of the Children's Defense Fund. In the past few years, we have become increasingly concerned about the immunization status of American children. The immunization rates of American children are stagnating overall and even declining for some crucial age groups. At a time when UNICEF and third world nations are conducting a world-wide campaign to immunize children against preventable diseases, U.S. leadership must not fail our children. We view this hearing as an indication of your concern and a positive step toward reversing this course.

The current AIDS epidemic provides some clues to life in the pre-vaccine era when children and adults died of many common contagious diseases for which there was no medical intervention to prevent or cure infection. While it is far more difficult to transmit AIDS than many other infectious diseases, not since the pre-vaccine days of polio has the American public been made so acutely conscious of the importance of vaccines in controlling and stopping the spread of a deadly disease.

Today, as a result of more than a century of research, vaccines are available to prevent illness, disability, or death from a number of communicable diseases. The use of vaccines to prevent disease has been one of the major success stories in public health and modern medicine. Among the greatest successes are the eradication of smallpox worldwide and the dramatic reduction in the incidence of polio in the United States.

To protect public health, a high level of immunization throughout the population must be achieved and maintained to prevent outbreaks of vaccine-preventable disease. A high immunization penetration rate plays two roles. First, it is a crucial method for protecting persons (particularly infants and young children) not yet fully immunized. Second, a consistently high penetration rate ultimately can lead to the

25

complete eradication of a disease. Thus the system for childhood immunization is crucial for the prevention of infectious disease both on an individual and community-wide basis. The failure of this system can lead to disease outbreaks.

Recent statistics from the Centers for Disease Control indicate that cracks have developed in our childhood immunization system. My testimony reviews the nation's progress toward meeting the Surgeon General's 1990 Objectives for the nation for increasing childhood immunization rates and reducing the incidence of certain diseases. It also examines the adequacy of public immunization funding levels and federal immunization monitoring and surveillance activities. To close, I will discuss the steps essential to protect all children with immunizations.

The National Rate of Progress Toward Meeting The Surgeon General's 1990 Immunization Status Objectives

Childhood immunization rates are falling, and the nation is moving away from the Surgeon General's Objectives for the improvement of immunization services for preschool age children.

TABLE 1. Recommended Immunization Schedule for Infants and Children*

Recommended Age**	Vaccines
2 months	Diphtheria, Tetanus, and Pertussis (DTP)-1 Oral Polio Vaccine (OPV)-1
4 months	DTP-2, OPV-2
6 months	DTP-3
18 months	Measles, Mumps, and Rubella (MMR) DTP-4, OPV-3
4-6 years (up to seventh birthday)	DTP-5, OPV-4
14-16 years (and every 10 years thereafter)	Adult Tetanus and Diphtheria (Td)

*Alternative schedules are recommended for children delayed in beginning immunizations and for certain chronically ill children.

**These recommended ages are not absolute. For example, 2 months may be 6-10 weeks of age.

Source: Recommendation of the Immunization Practices Advisory Committee. Morbidity and Mortality Weekly Report, January 14, 1983. Revised September 19, 1986.

In 1978 the Surgeon General of the United States set a number of modest 1990 Objectives for the Nation in the area of immunization. In the area of childhood immunization the following two objectives for improving services were set:

- By 1990, 90 percent of all children should have completed the basic immunization series by age two (measles, mumps, rubella, polio, diphtheria, tetanus, and pertussis).
- By 1990, at least 95 percent of children attending licensed day care facilities and kindergarten through twelfth grade should be fully immunized.

In the case of the childhood immunization goals for children attending school or licensed day care programs, the nation either has already or will achieve the goal. However, many children who receive child care in unlicensed programs are outside of this goal and related data collection efforts.

With respect to the goal for children at age two, however, unless a major effort is undertaken between now and 1990, the nation will not reach the objective or even come close. Statistics from the U.S. Department of Health and Human Services show that in 1985 a smaller percentage of children age two and younger were fully immunized against polio, measles, rubella, mumps, diphtheria, pertussis, and tetanus than in 1980 (Table 2). These data show that the nation's route of progress toward meeting this objective has either remained flat or actually declined in the case of several diseases (Figure 1).

TABLE 2. Progress Toward the Surgeon General's Objective for Full Immunization for Children Age Two

Year	POLIO*	MEASLES	RUBELLA	MUMPS	DTP*
1980	80.7	83.0	83.2	80.2	87.0
1981	80.9	81.5	83.9	79.1	87.6
1982	78.6	84.3	81.1	79.0	88.4
1983	78.6	83.9	81.9	78.1	88.4
1984	74.2	81.7	76.7	78.4	85.8
1985	76.7	81.7	77.3	78.9	85.8
1990 Objective	90.0	90.0	90.0	90.0	90.0

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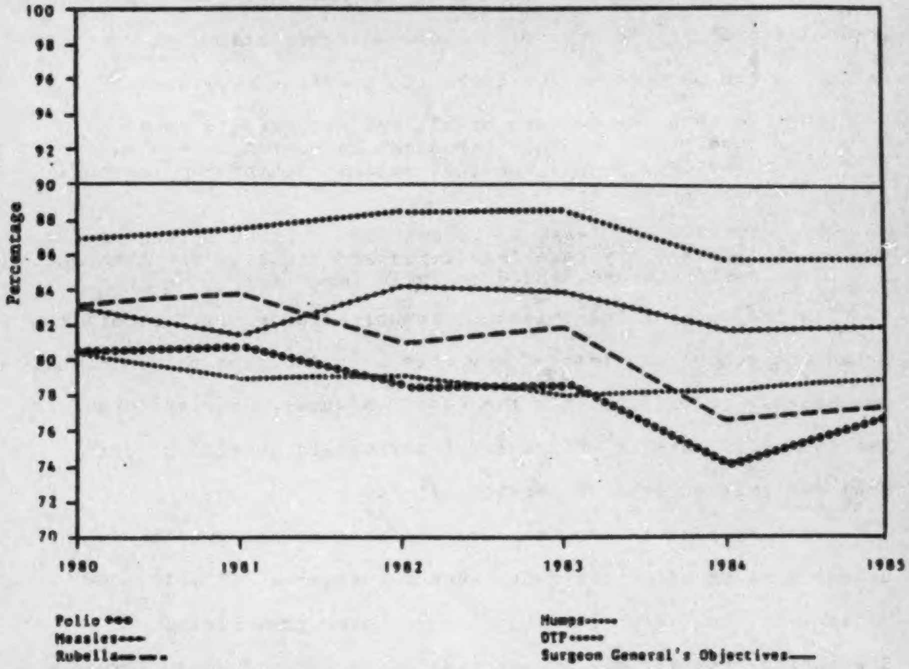
*Full immunization at this age is defined as three or more vaccinations.

Source: Data from Centers for Disease Control, U.S. Immunization Survey.

FIGURE 1. Progress Toward the 1990 Objective: Percentage of Children Age Two Who Were Fully Immunized, U.S., 1980-1985



Childhood immunization rates for specific diseases are particularly problematic.

In addition to the data on immunization status for two year olds, until 1985 the federal government collected data showing immunization rates for children of all ages. The 1985 statistics for children younger than age 5 show that for most diseases immunization rates are disturbingly low.

__Polio__: The polio vaccine must be given through a series of doses (four in all) to achieve immunity by age seven. While any dosage is better than none, full and long-lasting immunity is not provided until all doses have been administered appropriately (Table 1).

- During the preschool years, three doses of polio vaccine are recommended. Yet the percentage of age one to four children receiving no doses of polio vaccine increased between 1980 and 1985. As a result, by 1985 nearly one in 10 nonwhite children had received no dose of polio vaccine, and 39 percent of nonwhite children that age were not fully immunized (Figure 2).
- To be adequately immunized against polio, infants should receive a dose of polio vaccine at 2 months and

another dose at 4 months of age. Yet by 1985, 20 percent of all infants and 40 percent of nonwhite infants had not received the recommended two doses (Figure 3).

FIGURE 2. Percentage of Children Age 1-4 Years Who Had Received No Doses of Polio Vaccine, by Race, U.S., 1980-1985

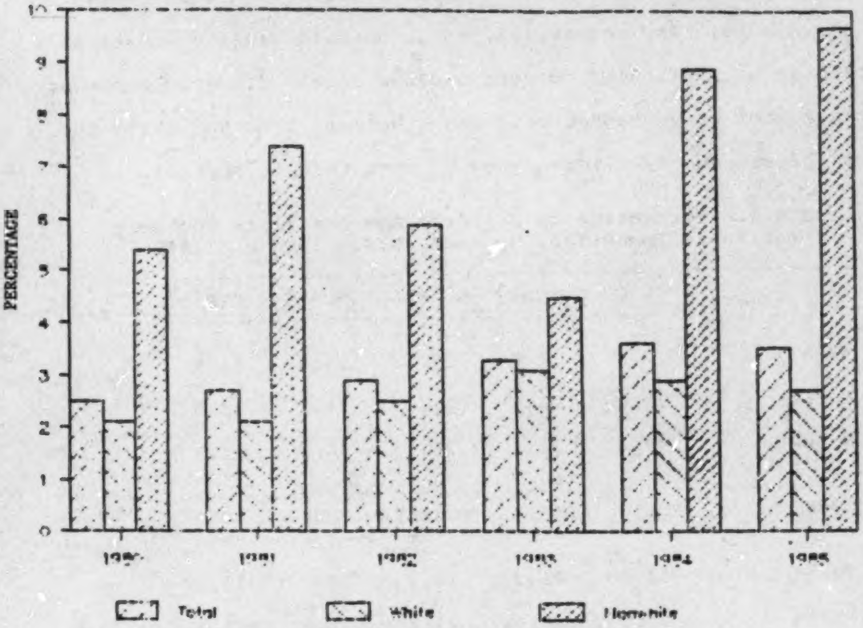
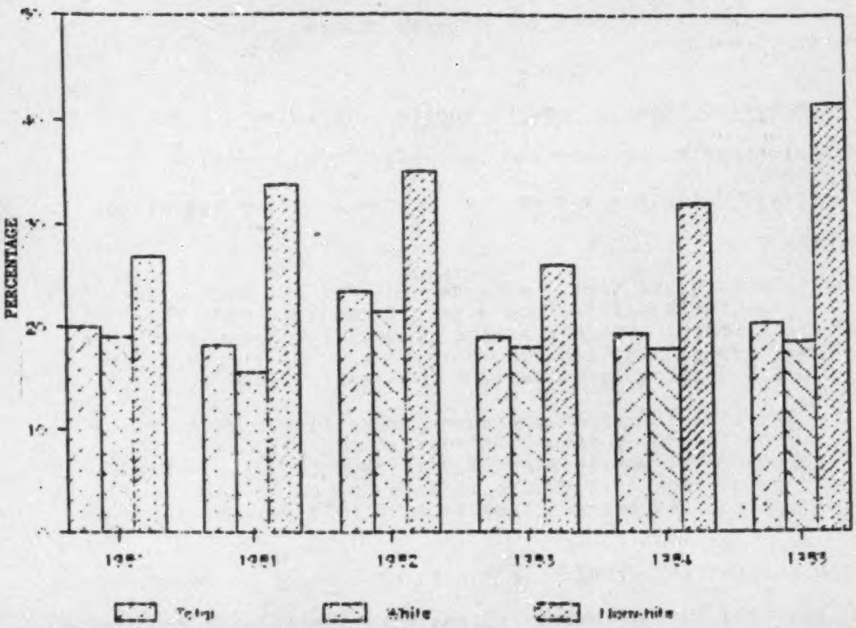


FIGURE 3. Percentage of Children Younger than Age One Not Fully Immunized Against Polio, by Race, U.S., 1980-1985



Because administration of the polio vaccine to children begins at two months, the increase in the number of very young children who had received no or inadequate numbers of doses also may be a proxy indicator of an overall decline in access to basic pediatric care. The possibility of an overall decline in access to care is of particular concern because of the dramatic increase in the number of uninsured children. Between 1982 and 1985, the number of uninsured children grew by more than 16 percent.

TABLE 3. Percentage of Children Age 1-4 Years Who Were Not Fully Immunized, By Race, U.S., 1980 and 1985

1980	POLIO	MEASLES	RUBELLA	MUMPS	DTP
Total	22.3	21.7	22.5	25.6	14.9
White	20.0	20.5	21.8	24.3	13.0
Nonwhite	42.0	31.4	28.7	36.9	31.5

1985	POLIO	MEASLES	RUBELLA	MUMPS	DTP
Total	24.3	21.2	24.5	22.5	13.0
White	22.5	20.0	23.3	21.2	11.5
Nonwhite	38.5	31.0	34.1	32.7	24.8

Source: Data from Centers for Disease Control, U.S. Immunization Survey.

Diphtheria, Tetanus, and Pertussis: Immunizing a child against diphtheria, tetanus and pertussis (DTP), requires administration of three dosages by age one and five dosages by age seven.

- Despite the great fears raised over the pertussis vaccine's deleterious side effects in a very few instances, the percentage of children age one to four years with no reported dosages rose only from 0.7 to 0.8 percent (a 14 percent increase) (Table 4).
- At the same time, the number of children younger than one not fully immunized against DTP climbed by 10 percent, from 15.8 to 17.3 percent overall, while the percentage of nonwhite infants not fully immunized climbed 68 percent from 21.0 to 35.2 percent (Figure 4).

The substantial erosion in the proportion of children not fully immunized for DTP suggests that access problems, combined with the need to ration a shrinking supply of pertussis vaccine because of a withdrawal of manufacturers from the market in 1984, were factors related to DTP immunization status declines between 1980 and 1985.

TABLE 4. Percentage of Children Age 1-4 Years Who Had Received No Doses of Vaccine, by Race, United States and Large Cities, 1980 and 1985

All Children

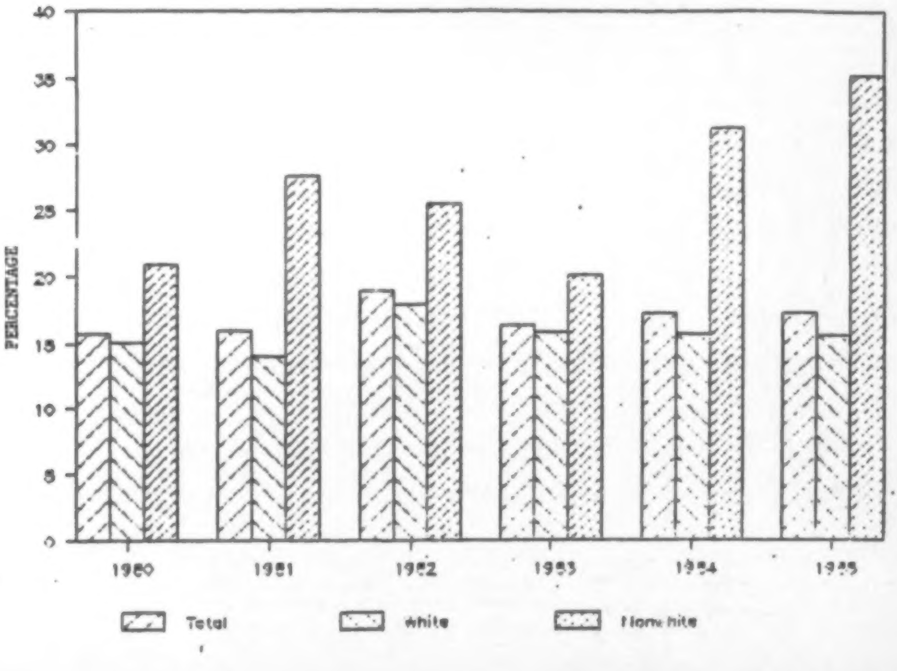
1985	POLIO	MEASLES	RUBELLA	MUMPS	DTP
Total	3.5	21.2	24.5	22.5	0.8
White	2.7	20.0	23.3	21.2	0.6
Nonwhite	9.7	31.0	34.1	32.7	2.1

Urban Children

1985	POLIO	MEASLES	RUBELLA	MUMPS	DTP
Total	3.6	24.3	28.1	26.4	0.9
White	2.4	22.1	26.0	23.8	0.4
Nonwhite	7.4	31.5	34.7	34.6	2.5

Source: Data from Centers for Disease Control, U.S. Immunization Survey.

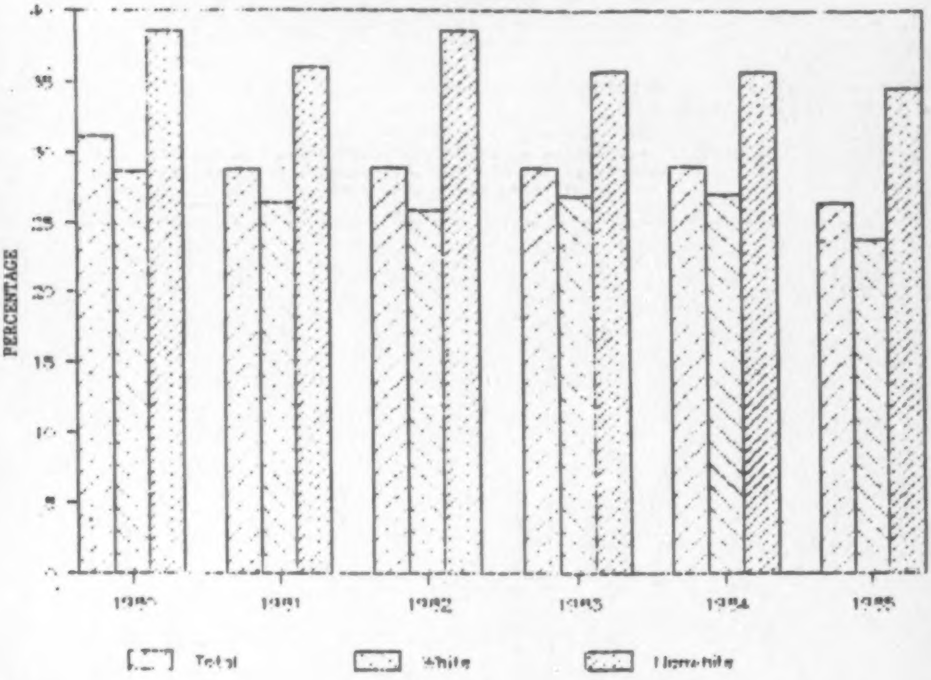
FIGURE 4. Percentage of Children Younger than Age One Not Fully Immunized Against Diphtheria, Tetanus, and Pertussis, by Race, U.S., 1980-1985



Mumps: A single vaccination recommended at age 18 months* fully immunizes a child against mumps (Table 1). Children are therefore either immunized or they are not. The mumps vaccine generally is given in combination with the measles and rubella vaccines (called MMR).

- Levels of immunization for mumps are inadequate among all children age one to four years, and the percentage of children who were vaccinated against mumps declined somewhat over the 1980-1985 period. However, for nonwhite children the problem is particularly severe--one-third of nonwhite preschoolers have never been vaccinated against mumps.
- Immunization levels in the nation's largest cities generally are depressed and low mumps immunization levels in urban areas exemplify this problem. In 1985 in the nation's largest cities, 26 percent of children and 35 percent of nonwhite children ages one to four years had received no doses of mumps vaccine (Figure 5).

FIGURE 5. Percentage of Children Age 1-4 Years Not Fully Immunized Against Mumps, by Race, Large Cities, 1980-1985



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* In 1986 the Immunization Practices Advisory Committee recommended that the combined measles, mumps, and rubella (MMR) vaccine be given at age 18 months. Many providers continue to provide the vaccine at a separate visit at 15 months of age.

As in the case of other vaccines, the mumps immunization problem in large cities suggests the presence of a more pervasive health care access problem for low-income children, either because of the lack of adequate primary care providers to serve uninsured families or the inaccessibility or inappropriateness of services furnished to Medicaid-enrolled children by managed care plans.

Measles and Rubella: Like mumps, the measles and rubella vaccines are to be administered once (generally at the same time in the MMR immunization).

- Between 1980 and 1985 virtually no progress was made in increasing the percentage of children ages one to four who had received doses of measles vaccine (a 2 percent change).
- In terms of rubella, by 1985 only 24.5 percent of children of all races (a 9 percent increase over 1980) and 34.1 percent of nonwhite children had received no doses (a 19 percent increase over 1980) (Table 3).

These statistics are indicators of a broad trend away from adequate immunization status between 1980 and 1985. There is a continued, distressingly high number of infants, toddlers and other preschool age children (particularly nonwhite children) who are not fully immunized against polio, DTP, measles, mumps, and rubella (Table 3). As with other health indicators, there exist gross racial disparities in immunization rates, but evidence from large cities suggests that these disparities are linked to economic status, not race. Thus, it appears that, as with other health care access issues, it is the poorer families most dependent on public forms of financing that are the least likely to receive care.

The National Rate of Progress in Reducing Preventable Childhood Disease

Certain disease rates are increasing and at current rates, the United States will not meet the Surgeon General's Objectives for reduction of disease rates for measles, mumps, and pertussis.

In addition to immunization status objectives, the Surgeon General in 1978 set goals for the improvement of health status by reducing the incidence of vaccine-preventable childhood disease. The goals specify that by 1990:

- Measles incidence should be reduced to fewer than 500 reported cases per year;
- Mumps incidence should be reduced to fewer than 1,000 reported cases per year;
- Rubella incidence should be reduced to fewer than 1,000 and congenital rubella syndrome incidence should be reduced to fewer than 10 cases per year;
- Diphtheria incidence should be reduced to fewer than 50 reported cases per year;
- Pertussis incidence should be reduced to fewer than 1,000 reported cases per year;
- Tetanus incidence should be reduced to fewer than 50 reported cases per year;
- Polio incidence should be reduced to fewer than 10 reported cases per year.

TABLE 5. Trends in Reported Cases of Selected Diseases, U.S., Selected Years 1960-1985

Year	POLIO	MEASLES	RUBELLA	MUMPS	DIPHTHERIA	TETANUS	PERTUSSIS
1960	3,190	441,703	---	---	918	368	14,809
1965	72	261,904	46,975*	152,209**	164	300	6,799
1970	33	47,351	56,552	104,953	435	148	4,249
1975	8	24,374	16,652	59,647	307	102	1,738
1980	9	13,506	3,904	8,576	3	95	1,730
1981	6	3,124	2,077	4,941	5	72	1,248
1982	8	1,714	2,325	5,270	2	88	1,895
1983	15	1,497	970	3,355	5	91	2,463
1984	8	2,587	752	3,021	1	74	2,276
1985	7	2,822	630	2,982	3	83	3,589
1986	3	6,282	551	7,790	0	64	4,195
1990 Objective	10	500	1,000	1,000	50	50	1,000

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* Number is for 1966, the first year that rubella cases were routinely reported.

**Number is for 1968, the first year that mumps cases were routinely reported.

Source: Data from Centers for Disease Control. Summary of Notifiable Diseases, United States, 1986, September 25, 1987.

As Table 5 indicates, however, based on 1980-1985 trends, the United States is moving away from the goals for measles, mumps, and pertussis. If recent trends hold, the United States will meet the polio, diphtheria, and rubella/congenital rubella goals, each of which had been met by 1980 and require only a maintenance of effort through 1990. However, the declining proportion of children immunized for polio, diphtheria, and rubella and shifts such as those which occurred in reported cases of polio and tetanus in 1983 (and a similar rise in cases of congenital rubella in 1986) indicate a cause for concern over whether past progress in reducing disease incidence will hold.

Recent trends in cases of targeted childhood diseases are troubling.

To fully grasp the potential and actual impact of immunization, it is necessary to understand each target disease and how vaccines have affected trends in that disease. Generally, the widespread use of vaccines has resulted in dramatic reductions in the number of cases of each of the seven targeted diseases: polio, measles, mumps, rubella, diphtheria, pertussis, and tetanus. An eighth disease, smallpox, has been eradicated and children are no longer immunized against it. Immunization against a ninth disease -- a bacteria that is the leading cause of bacterial meningitis -- recently has become available.

Because the nation has not eliminated any major childhood disease (except smallpox), the potential for infection still exists in every community. In fact, recent significant increases in cases of measles and pertussis are a particular cause for concern and show the results of a failure to keep striving for virtually universal immunization.

Polio: Poliomyelitis (polio) is a contagious viral disease that was formerly known as infantile paralysis. Most polio virus infections -- 80 to 90 percent of cases -- are "minor illnesses." They cause no symptoms or only result in a mild upset of the digestive tract with slight fever, sore throat, or headache. Major illness with polio begins with similar symptoms, but severe muscle pain is usually present. The infection may affect the spinal cord, and paralysis may occur.

Tens of millions of Americans are too young to remember the tremendous fear of polio that gripped this country and the extraordinary relief that the Salk vaccine unleashed. The polio epidemics of the first half of this century resulted in disability for tens of thousands of Americans and deaths for thousands more. Widespread use of the Salk vaccine beginning in the mid-1950s brought about perhaps the most visible immunization success story of the modern era. Since the mid-1970s there has been an average of only 13 cases of polio reported each year.

Yet because many cases of polio occur around the world each year, the need for high rates of vaccination among American children against polio remains critical.

Measles: Measles, also called rubeola, is a highly contagious viral disease. For most people, measles begins like a cold, with a rash appearing a few days later and lasting one to two weeks. Measles can cause very serious illness. It can lead to middle ear infections, pneumonia (especially in infants), an inflammation of the brain (encephalitis) leading to convulsions, permanent brain damage, or death, or a chronic nervous system infection (subacute sclerosing panencephalitis -- SSPE) leading to severe disability or death. Death occurs in one of every 3,000 reported measles cases.

Before the vaccine became available, more than 400,000 measles cases were reported each year. By 1968 the number of reported cases had dropped to just over 22,000. Throughout the early 1970s the number of cases fluctuated, averaging 36,500 between 1968 and 1978. From 1977 to 1978 and again from 1978 to 1979, the number of reported measles cases dropped by half (from approximately 57,000 to 27,000 and from 27,000 to 13,500, respectively). These declines occurred primarily as a result of a Measles Elimination Program introduced by federal officials in 1978 that sought to eradicate measles in the United States by 1982. By 1981 there were slightly more than 3,000 cases, but after dropping to a low point of about 1,500 cases in 1983, provisional nearly 6,300 measles cases were reported in 1986.

The CDC reports that failure to eliminate indigenous measles is related to failure to implement the campaign and that approximately one-third of all measles cases were preventable through immunization.

The recent increases in reported measles cases occurred in all age groups, but the highest rates have been reported among preschool-age children. This was the result of several outbreaks of measles among preschool-age children living in poor, urban areas. Of the nearly 2,500 cases reported among children under age 5 in 1986, half were among those age 16 months to four years. The CDC has found that 83 percent of reported measles cases among children 16 months to four years in that year were preventable. Low immunization levels among preschoolers, particularly among poor preschoolers in densely populated urban areas, have been reported widely by the CDC.

Research has shown that the first decade of measles vaccination programs saved more than $1 billion in health care costs. Generally, for every dollar spent on measles vaccination $10 can be saved in productivity and medical resources.

Mumps: Mumps is a communicable disease that, in younger children, usually causes mild symptoms, including fever and and inflammation of the neck and face. Sometimes it has more serious complications, such as inflammation of the brain and spinal cord coverings (meningitis) or other central nervous system involvement, as well hearing impairment. Among male teens or adult men mumps can lead to swelling of the testicles (orchitis) and possibly sterility.

Mumps became a reportable disease in 1968, and in that year more than 152,000 cases were reported. Yet because of a higher vaccination cost and lower priority than measles and rubella, it was not until 1977 that routine use of mumps vaccinations was officially recommended. Between 1978 and 1980, the number of cases was cut almost in half (16,800 down to 8,600). The number of reported cases continued to decline through 1985.

In 1986, after 15 years of almost continuous decline in the reported incidence of mumps, a nationwide increase in cases was reported. The CDC data show a more than doubling of mumps incidence from 2,982 in 1985 to 7,790 cases in 1986. Furthermore, for the first six months of 1987 the more than 9,000 cases of mumps reported were more than four times the number reported during the comparable period of 1986, and were higher than the number of cases reported in any of the preceding five years. The CDC statistics suggest that recent increases largely have been a result of illness among unvaccinated teens, however even among infants the reported number of cases grew from 29 in 1985 to 142 in 1986.

Rubella: Rubella, also called German or three-day measles, is generally a mild but highly contagious viral illness for children. In the mild form, it causes a slight fever, a rash on the face and neck, swollen glands, and discomfort for two to three days. Half of infections cause no symptoms at all, and complications from rubella are rare. However, where rubella spreads to teenagers and young adults, it can infect pregnant women. During pregnancy, especially during the first trimester, rubella can cause miscarriage, stillbirth, or multiple serious birth defects. Common birth defects associated with congenital rubella include low birthweight, blindness, deafness, jaundice, mental retardation, and heart defects.

The last big epidemic of rubella was in 1964-1965, when an estimated 12.5 million cases, more than 11,000 fetal deaths, and 20,000 instances of birth defects from congenital rubella occurred. By 1986, there were only 551 cases of rubella. In that year, there were 14 cases of congenital rubella syndrome reported (this number has shown wide fluctuation in recent years).

Diphtheria: Diphtheria is an infectious disease caused by a bacterium found in the mouth, nose, and throat of infected persons. It generally develops in the throat, where a thick, false membrane may form and interfere with swallowing or breathing. In some cases, especially when untreated, diphtheria can produce a toxin that may spread throughout the body and cause serious complications, such as heart failure, pneumonia, or nervous system damage.

Widespread immunization against diphtheria has greatly reduced the number of reported cases. In the 1920s, approximately 150,000 to 200,000 cases of diphtheria and 15,000 to 20,000 related deaths occurred annually. There were just more than 900 cases in 1960, more than 400 cases in 1970, about 50 cases in 1979, no more than five cases in any year between 1980 and 1985, and no cases in 1986.

Tetanus: Tetanus, also known as lockjaw, is caused by a bacterium that exists in virtually every part of the environment but is found in high concentrations in soil, dust, manure, and the digestive tracts of humans and animals. Tetanus enters the body through a small or large wound (most often through puncture wounds). Once inside the body, tetanus multiplies and produces a toxin that causes muscle stiffness and spasms. The first symptoms often include stiffness in the jaw and neck. Tetanus can be very serious, and is often fatal for the young and the aged. Because even an episode of the disease does not create immunity, immunization with tetanus toxoid is particularly important.

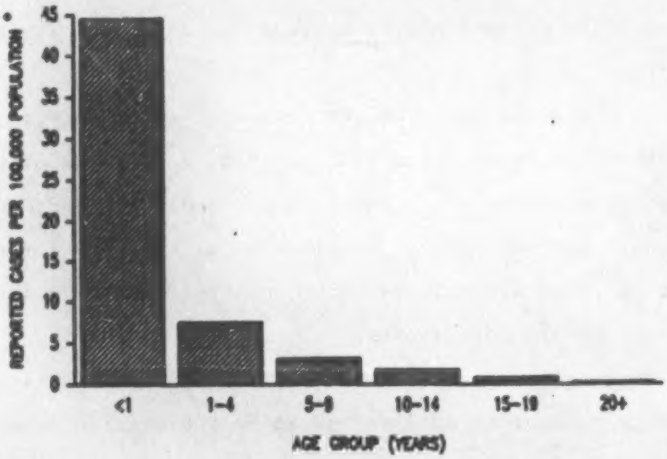
In the 1940s more than 600 cases of tetanus often were reported in a year. From 1955 to 1965, an average of 800 cases was reported annually. In the past decade, the incidence of pertussis has not changed substantially, however, the number of cases was down slightly in 1986. Currently, most cases (95 percent) occur among adults.

Pertussis: Pertussis, commonly known as whooping cough, is a highly contagious disease caused by a bacterium found in the mouths, noses, and throats of infected persons. It causes severe spells of coughing that can interfere with eating, drinking, and breathing. For children younger than two, pertussis can be quite serious. It is fatal for 1 to 2 percent of infected infants, but even children who survive serious complications may be left paralyzed, mentally retarded, or otherwise impaired.

The pertussis vaccine used today is made of whole, killed bacteria and contains agents that may cause adverse reactions for some individuals. Furthermore, the currently used pertussis vaccine does not provide complete immunity. Research is currently under way to improve the pertussis vaccine.

At the same time, the current vaccine, along with improvements in the standard of living and public health, have reduced dramatically the incidence of pertussis. Furthermore, mortality among those who do become infected has declined as antibiotics have become available for treatment. The incidence of pertussis dropped from a reported high of more than 250,000 in 1934 to a low of 1,248 cases in 1981. It is of great concern, however, that the number of reported cases more than tripled between 1981 and 1986, reaching 4,195 -- the highest reported number since 1970. Rates of pertussis were especially high among infants (Figure 6).

FIGURE 6. PERTUSSIS (whooping cough) — By age group, United States, 1986



*Rates were calculated by multiplying the percentage of cases with known age group by total reported cases and dividing by the population in that age group.

Federal Immunization Programs to Reduce Preventable Childhood Disease

Funding for immunization efforts has failed to keep pace with vaccine price inflation.

From the time the polio vaccine became available in the 1950s, the federal government has assumed a leadership role in financing childhood immunization programs, conducting surveillance activities to determine progress in increasing immunization levels and decreasing disease levels, and conducting research activities designed to combat new diseases and more effectively and safely immunize against existing ones.

Generally, about one-half of all childhood vaccines are financed through the private sector -- either out-of-pocket or through private third-party (insurance) payments. The remaining half is financed publicly through a combination of federal and state programs. These public programs include the federal immunization states grants program (Section 317 of the Public Health Service Act), Medicaid (immunizations are a required service for all Medicaid-enrolled children), the Title V Maternal and Child Health Block Grant program, and the Community and Migrant Health Centers programs.

The Division of Immunization of the CDC serves as the federal agency most directly involved in the prevention and control of preventable childhood diseases. The CDC efforts are carried out through: 1) the program of project grants, and 2) direct program operations. The grant activities are structured under Section 317 of the Public Health Service (PHS) Act and provide for grants to state and local health agencies to allow them to plan, develop, and implement immunization programs.

The key to the entire system of vaccine purchase and administration is the Section 317 federal grant program to the states. But throughout the 1980s these grants have not been adequate to meet the need. Despite skyrocketing vaccine costs, neither the Reagan Administration nor Congress moved to expand funding levels significantly until FY 1985. Indeed, for FY 1982 the Administration proposed completely eliminating the program (by replacing it with a multipurpose block grant) and then cutting overall funding by 25 percent. Congress did not exempt immunizations from the Gramm-Rudman-Hollings automatic spending reduction requirements, and as a result in FY 1986 the program lost $2.3 million. Funding levels were increased from FY 1986 to FY 1987 (from $45.3 million to $75 million) and again between FY 1987 and FY 1988 (to $93. million).

Even the growth in federal childhood immunization program funds that has occurred has not meant a growth in federal immunization efforts.

There are three reasons for this. First, the number of children younger than six has increased over the past decade, from 18.8 million in 1979 to 21.7 million in 1986.

Second, the number of poor and uninsured children has increased dramatically. The number of poor children younger than six increased from 3.4 million in 1979 to 4.8 million in 1986. Between 1982 and 1985 alone, the number of uninsured children increased by more than 16 percent. While the federal immunization program and other federal child health funding programs (with the exception of Medicaid) are not limited to poor children, the growth in poor and uninsured children gives a sense of the heightened need for public immunization programs among families that cannot afford private care for children.

Third, and most important in the immunization context, the cost of vaccines has skyrocketed, particularly in the 1981-1986 period. In 1986 measles vaccine cost nearly three times as much per dose as in 1980 and polio vaccine more than four times as much. The price of DTP vaccine is reported to have increased by 2,000 percent from 1982 to 1985. By 1986 it took three times as many federal immunization grant dollars to purchase roughly the same number of vaccine doses that were bought in 1980. Even adjusting for general rates of inflation most vaccines cost two to four times as much in constant dollars in 1986 as in 1980.

Given this huge increase in cost per dose, the modest increases in federal spending through 1986 have in fact meant fewer public doses delivered. Each year in the 1981-1986 period there have been fewer doses administered in the public sector than in each year between 1978 and 1980. The 1986 total was estimated to be only 80 percent of the doses delivered in 1979.

Rising vaccine costs also affect the availability of immunizations through the private sector. Private physicians have reported that many families are unable to afford immunizations at the private pay rate. As a result, there is evidence that families who would have obtained immunization services from private physicians increasingly have sought immunizations at already overburdened public health clinics.

Despite the fact that surveillance has been identified as an essential element of immunization efforts, the CDC has discontinued the U.S. Immunization Survey (USIS), which had provided an annual snapshot of immunization levels.

The USIS data are not available for years after 1985 and other national survey systems do not adequately track immunization levels. While reporting systems for disease cases and record collection from schools and day care centers remain in place, these cannot substitute for a national survey of childhood immunization status. Without such surveillance, there will be no opportunity to track decreases in immunization status and respond appropriately. The elimination of immunization surveillance at this time is particularly troubling in light of the declines in the immunization status of our youngest children that occurred between 1980 and 1985.

Despite fewer doses being delivered, falling immunization rates, and rising disease rates, the Administration has not sought aggressively to reinvigorate the flagging federal immunization effort.

This vacuum of leadership has occurred even though the past has shown that intensive federal efforts make a difference. For example, in 1977-1978, substantial federal action was taken in response to declining immunization levels. The Secretary of Health, Education, and Welfare, Joseph Califano, Jr., launched two major initiatives: one aimed at raising immunization levels to 90 percent by October 1979, and the other aimed at the eradication of measles in the United States by 1982. The latter initiative outlined three keys to a successful immunization program: 1) achievement and maintenance of high immunization levels; 2) development of strong and effective surveillance systems; and 3) aggressive response to disease outbreaks. The testament to the success of this three-pronged initiative is the measles statistics for the ensuing years. In 1977 more than 57,000 cases were reported, in 1978 only 27,000, in 1979 and 1980 only 13,500, and in 1981 slightly more than 3,000 -- a 95 percent decrease for the period.

Congress has tried to assure vaccine availability, which is essential to the success of our national immunization effort and must be made a priority.

Vaccine availability is another important factor in the success of the nation's efforts to reduce preventable childhood disease. There are two aspects to availability: a continuous, reliable supply of vaccines must be manufactured; and vaccines must be made available at an affordable price to providers and families. Each factor independently influences availability.

In recent years, concern has been growing regarding the availability of vaccines. Current problems with the supply of vaccines include: limited numbers of manufacturers and concentration of production of individual vaccines among a small number of suppliers (one or two per vaccine); limited stockpiling (storage and preservation) of vaccines to be used in the case of interruptions in supply; and market and liability concerns that have made vaccine production relatively unattractive to commercial manufacturers. In 1984, for example, these factors combined caused a crisis in the availability of the DTP vaccine that required cutbacks in the immunization schedules of many children. Moreover, the CDC vaccine stockpile continues to be less than the amount needed for six months coverage. (The CDC currently considers a six-month stockpile a goal, but other experts have suggested that an even greater stockpile should be maintained.)

In 1986 and 1987, Congress passed the National Childhood Vaccine Injury Act (P.L. 99-660) for the purpose of creating a system to compensate children for injuries received from routine pediatric immunizations and reduce the liability of manufacturers in order to hold down vaccine price inflation. This act, which was supported by many consumer groups, provider groups, and manufacturers, established the basic structure for a new vaccine compensation system.

The actions taken were designed to ensure that that a fair system of compensation would be available for children injured from vaccines administered in the future. However, the success of this system depends on: the appropriation of funds to allow families with children suffering from past vaccine-related injuries to be compensated appropriately; the adequate collection of vaccine excise taxes which would be placed in a trust fund from which future claims may be paid; and the joint cooperation of Congress, the Department of Health and Human Services, vaccine manufacturers, and families.

RECOMMENDATIONS AND CONCLUSIONS

There has been a substantial increase in the United States in the rate of measles and a resurgence of cases of mumps and pertussis. Immunization rates for our youngest children have leveled off or declined; and, if recent trends continue, the nation will fail to meet about half of the Surgeon General's 1990 objectives in the area of immunization.

In the 1980s, with the obvious exception of AIDS, the threat of serious communicable disease is quite small, and the serious epidemics of childhood disease of previous eras are history. Health care providers of today never had to face a hospital ward full of children sick from diphtheria or pertussis. Parents of today have never experienced the death and illness caused by childhood disease epidemics of the past. However, the eradication of preventable childhood disease must continue to be a national priority.

To ensure greater success, CDF recommends the following:

Appropriation of sufficient funds in the Immunization Program to enable the CDC to make vaccines available to all children. For children in families with income below the federal poverty, vaccines should be made available at no cost, and for all other children vaccines should be made available at an affordable cost. The President's budget calls for an additional $7 million for the Immunization Grants program. However, this amount is only sufficient to purchase the same number of vaccine doses as were provided in 1988. Data from the first half of the decade suggest that more doses are needed if we are to fully immunize all children. CDF recommends the appropriation of an additional $40 million for FY 1989, however, greater amounts may be needed by the CDC if the cost of the vaccines includes the newly applied excise taxes.

Funds appropriated for FY 1989 should allow CDC to continue support for the national immunization system, not just for the purchase of vaccines. Funds to purchase a sufficient number of doses of vaccine are essential, as is having a sufficient number of health care providers available to vaccinate children. However, direct service delivery is only one aspect of our national system. The CDC also has responsibility for program operations through which it conducts certain activities more efficiently and effectively accomplished through a central agency. Among these operations are: coordination, surveillance, outbreak control, education and outreach, and other public health supervisory activities. The FY 1988 funding levels and the proposed FY 1989 funding levels are not sufficient to allow both for the purchase of the same number of doses of vaccine and the maintenance of CDC support for state activities. In fact at the funding level proposed for FY 1989, $19 million would have to be cut out of central administrative support to allow the CDC to maintain the number of doses of vaccine. Because these central activities both support the states and ensure a national system to prevent childhood disease, they must be continued.

A continued commitment to maintenance of the vaccine stockpile. The storage and preservation of vaccines in a stockpile is a key component of the national effort to ensure the availability of vaccines. Appropriations levels for the vaccine stockpile should be sufficient to allow for at least a six months supply of vaccine.

H.R.2122 and S.4072, the Medicaid Infant Mortality Amendments of 1988 should be enacted immediately. These bills would extend Medicaid coverage to all poor infants in FY 1989. Enactment of these provisions could ensure the financing of immunizations for tens of thousands of low-income children.

Restoration of the immunization surveillance system or replacement of the prior system with a new annual immunization survey. Other national health surveys do not provide adequate information regarding immunization status. Given certain adverse trends in immunization status and recent outbreaks of diseases across the nation, abandoning this system is a serious mistake in public health terms. Comprehensive surveillance activities, based on a national survey, should be resumed as soon as possible to chart progress for the end of this decade

Appropriation of sufficient funds to provide fair compensation for families with children suffering from injuries related to vaccines which were administered before October, 1988. These funds are urgently needed and should be made available at the soonest possible opportunity. The authorization level for this account for FY 1988 was set at $80 million.

Congress and the U.S. Department of Health and Human Services should begin now to adopt policies which can assure an adequate system for providing childhood immunizations by 1992. Meeting the Surgeon General's Objectives, by even that year, will require a commitment such as was made during the late 1970s, including: continued increases in funding levels for key child health programs to compensate for vaccine price inflation; aggressive efforts to improve and sustain immunization levels; studies of disease outbreaks and their causes; public education campaigns regarding the importance of childhood immunizations; and ongoing surveillance of a detailed nature.

The U.S. Office of Technology Assessment (OTA) has recently released a landmark report entitled Healthy Children: Investing in the Future. In that report, they concluded that: "the cost-effectiveness of childhood vaccines is well established." OTA has reported that such vaccines have been found not only to be of medical benefit, but also to be cost-saving. At the same time, the report documents our failure to immunize our youngest children--with immunization levels for American infants significantly lower than several other industrialized countries; and the considerable differences in immunization status which persist with respect to race and geographic location.

This nation cannot afford preventable illness, disability, or death among our children. We must act now to ensure that all children have access to affordable, safe vaccines and recommit ourselves to the goal of disease eradication where possible.

REFERENCES

This testimony is based on a recent report of the Children's Defense Fund (CDF):

Johnson K. Who is Watching Our Children's Health? The Immunization Status of American Children. Children's Defense Fund, Washington, DC, December 1987.

The majority of the statistics presented in that report and in this testimony came from the Centers for Disease Control (CDC). All references to immunization status and the U.S. Immunization Survey are from unpublished tables prepared by the Centers for Disease Control. Calculations of the percentage of children immunized by age were done by the CDC, and calculations of the percentage change over time were done by CDF.

Other sources used as background include the following:

Centers for Disease Control. "Summary of Notifiable Diseases, United States, 1986," Morbidity and Mortality Weekly Report, Vol. 35, No. 55, September 25, 1987.

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Miller CA, Fine A, Taylor SA, and Schorr LB. Monitoring Children's Health: Key Indicators, American Public Health Association, Washington, D.C., 1986.

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APPENDIX A. Percentage of Children Not Fully Immunized, By Age and By Race, U.S., 1980-1985

	INFANTS (<1 Year)			1-4 YEARS			5-6 YEARS		
	Total	White	Non-White	Total	White	Non-White	Total	White	Non-White
POLIO									
1980	20.0	19.1	26.8	22.3	20.0	42.0	25.5	22.8	51.2
1981	18.2	15.6	33.8	21.7	20.1	34.0	26.6	23.6	51.7
1982	23.4	21.4	35.1	21.6	19.6	37.1	25.0	22.6	44.1
1983	19.0	18.1	26.0	23.5	21.5	39.0	27.9	24.3	56.0
1984	19.3	17.8	32.0	26.3	24.1	43.3	24.5	22.5	41.2
1985	20.4	18.5	41.5	24.3	22.5	38.5	28.7	26.8	45.5
DTP									
1980	15.8	15.1	21.0	14.9	13.0	31.5	20.3	18.2	39.7
1981	16.0	14.1	27.6	13.1	12.3	19.7	18.9	16.1	42.2
1982	19.0	17.9	25.6	13.2	11.6	25.4	15.4	13.6	29.2
1983	16.4	15.9	20.2	14.0	12.5	25.8	17.8	15.9	32.8
1984	17.3	15.7	31.3	15.3	14.1	24.3	16.5	15.6	24.4
1985	17.3	15.6	35.2	13.0	11.5	24.8	14.9	13.4	28.2

APPENDIX B. Percentage of Children Age 1-4 Years Receiving No Doses of Vaccine, U.S. and Large Central Cities*, 1980-1985

Percent of All Children Receiving No Doses					
	Polio	Measles	Rubella	Mumps	DTP
Total 1980	2.5	21.7	22.5	25.6	0.7
Total 1981	2.7	22.4	23.1	25.5	1.0
Total 1982	2.9	20.6	22.3	22.9	0.7
Total 1983	3.3	20.7	21.9	23.4	1.1
Total 1984	3.6	21.7	24.5	24.7	1.8
Total 1985	3.5	21.2	24.5	22.5	0.8

Percent of Urban Children Receiving No Doses

	Polio	Measles	Rubella	Mumps	DTP
Cities 1980	3.6	25.7	28.6	31.2	1.3
Cities 1981	3.2	23.1	24.2	28.8	0.9
Cities 1982	5.8	26.4	27.1	29.0	0.9
Cities 1983	3.8	21.2	23.0	28.9	1.8
Cities 1984	3.8	24.0	26.9	29.1	3.5
Cities 1985	3.6	24.3	28.1	26.4	0.9

Percent of All White Children Receiving No Doses

	Polio	Measles	Rubella	Mumps	DTP
Total 1980	2.1	20.5	21.8	24.3	0.6
Total 1981	2.1	21.5	22.6	24.9	0.7
Total 1982	2.5	19.7	21.0	21.7	0.7
Total 1983	3.1	20.8	21.8	22.7	1.0
Total 1984	2.9	20.7	23.1	23.5	1.5
Total 1985	2.7	20.0	23.3	21.2	0.6

Percent of Urban White Children Receiving No Doses

	Polio	Measles	Rubella	Mumps	DTP
Cities 1980	2.3	23.0	27.7	28.7	1.0
Cities 1981	2.3	20.7	22.8	26.5	0.3
Cities 1982	5.5	23.6	24.6	26.0	1.0
Cities 1983	3.5	21.2	22.9	27.0	1.7
Cities 1984	2.5	23.0	24.1	27.1	2.8
Cities 1985	2.4	22.1	26.0	23.8	0.4

Percent of All Nonwhite Children Receiving No Doses

	Polio	Measles	Rubella	Mumps	DTP
Total 1980	5.4	31.4	28.7	36.9	1.5
Total 1981	7.4	29.8	26.5	30.0	2.9
Total 1982	5.9	27.7	31.8	32.2	1.2
Total 1983	4.5	19.7	22.8	29.1	1.3
Total 1984	8.9	29.7	34.9	34.0	4.2
Total 1985	9.7	31.0	34.1	32.7	2.1

Percent of Nonwhite Urban Children Receiving No Doses

	Polio	Measles	Rubella	Mumps	DTP
Cities 1980	7.4	33.9	31.2	38.6	2.5
Cities 1981	5.9	30.9	28.6	36.0	3.0
Cities 1982	6.6	35.0	35.1	38.6	0.8
Cities 1983	4.8	21.1	23.3	35.7	2.0
Cities 1984	7.9	27.3	36.0	35.7	5.5
Cities 1985	7.4	31.5	34.7	34.6	2.5

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*Data in this table include immunization rates for all U.S. children and for those children living in the central city areas of the Standard Metropolitan Statistical Areas as defined by the U.S. Census Bureau.

APPENDIX C. Price Per Dose Of Selected Vaccines Purchased Under Federal Contracts, 1975-1986

	MMR*		POLIO**	
Year	Constant (1978) Dollars	Actual Dollars	Constant (1978) Dollars	Actual Dollars
1975	2.93	2.42	0.18	0.15
1976	2.77	2.42	0.21	0.19
1977	2.61	2.42	0.32	0.30
1978	2.35	2.35	0.31	0.31
1979	2.35	2.62	0.30	0.33
1980	2.14	2.71	0.28	0.35
1981	2.24	3.12	0.28	0.40
1982	3.04	4.50	0.39	0.58
1983	3.22	4.91	0.43	0.66
1984	3.39	5.40	0.46	0.73
1985	4.15	6.85	0.49	0.80
1986	5.09 ***	8.47	0.94	1.56

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*Measles, mumps, and rubella combined vaccine.
**Polio priced per dose for 10 dose units; MMR vaccines priced in single dose units.
***Adjusted price as of May 1986.

Source: U.S. House of Representatives, Subcommittee on Health and the Environment of the Committee on Energy and Commerce, Report on Childhood Immunizations, September 1986.

Senator BUMPERS. Thank you.
Dr. Coffin.

STATEMENT OF DR. ROBERTA COFFIN

Dr. COFFIN. Thank you very much, Senator Bumpers. I appreciate the opportunity to talk with you about the current status of the Childhood Immunization Program and the impact of the vaccine surtax on program funding in the States.

I am Dr. Roberta Coffin, the commissioner of health in the State of Vermont, and I am here representing the Association of State and Territorial Health Officials. I am a board-certified pediatrician.

On July 25, 1986, I represented ASTHO here in its support of the establishment of the vaccine injury compensation program. You are to be commended for the passage of the National Childhood Vaccine Injury Act.

The passage of that law created a new system but no funding to cover the surtax cost to States. I noted this as a potential problem in 1986 in my testimony that I presented at that time, and it is indeed a reality.

ASTHO has a high level of concern over past vaccine cost escalation and fears that the much-touted leveling off of these costs is not on the horizon as believed.

The increased dollars you have provided to CDC to purchase vaccines through Federal contracts is laudable; however, this covers the purchase of only about one-half of all public-supported vaccine.

Other Federal funds, such as the Maternal and Child Health Block Grant, which are used by States to support vaccine costs and to insure the successful administration of a childhood immunization program at the State level have been level funded or slightly increased at levels less than inflation rates for 7 years.

This is for States in increasing competition and demands for State and local funds in order to keep State childhood immunization programs constant.

You perhaps remember that Congress provided a special supplemental appropriation of $20 to $25 million for the purchase of DTP vaccine at the time of the original price explosion. This is an example of the infusion of significant funds which are needed now, probably on a one-time basis.

The new conjugated HIB vaccine, we are told, may cost as much as $7 to $8 instead of the $2 to $3 for the older polysaccharide HIB vaccine. No increased funds have been provided for this more age-appropriate vaccine. This adds additional costs on top of the surtax problems of State health departments.

Although you may provide apparently adequate dollars to CDC, States clearly understand, although we have received no official notification, that these are only adequate because of a shift in many dollars previously earmarked for direct State assistance for administering vaccine programs, such as provide public health advisors, coordination of

State programs, data collection for accountability, surveillance purposes, and so forth.

These are all important elements if we are to continue to be sure we are immunizing all our children.

Now, you might consider the State cost saving measures through increased efficiency could provide some needed dollars. States have already tightened their vaccine handling and purchase programs. In Vermont, 96.5 percent of vaccine is accounted for and administered.

The States are worried about families who cannot afford the even greater increases in vaccine costs due to the surtax which they face when they seek routine preventive pediatric care in private physicians' offices.

Many families face two options. The first is to go without immunizations; and the second is to seek a low-cost immunization in the public sector.

States face a big hurdle which we predict will not peak even for 6 months. We have information from a survey which we have done from 22 States. So far, this indicates a projected shortfall of $12 million.

I would like to give you just a few anecdotes which we gathered when we were doing this survey.

The nearby State of Virginia has seen an increase of 15 percent in the growth of public clinics since January of this year.

Senator BUMPERS. January 1988?

Dr. COFFIN. Yes; several larger pediatric practices have office signs saying you can get your child's immunization in a public clinic; but since November, the State has had two vaccine outages in public clinics and had to close those public clinics.

The State of Colorado has a projected 1988 shortfall of $131,000, resulting in a decision to save $62,000 by not purchasing HIB conjugated vaccine. This has been a recurring theme, I might add. We have heard this from several States.

In 1985 to 1986, they have shown an increase of 45 percent usage of public clinics providing DTP immunizations, and this required additional State funding.

The State of California is looking for funds to cover the cost of at least $1 million for vaccines.

Your support of funds to CDC to purchase vaccine at the fiscal year 1987 level is likely to be inadequate because the number of children younger than six has increased each year over the past decade.

In addition, there appears to be an absolute growth in the number of poor and underinsured children, which heightens the need for public immunization.

Vermont has always had a generous legislature. Vermont has always provided vaccine for all children in the State, whether administered in the private or public sectors. We have encouraged children to get comprehensive preventive health care from the same individual from whom they receive acute illness care.

Because Vermont, like all other States in the county, has a school entry immunization law, vaccine should be viewed as an entitlement. If we are to prevent a decrease in the number of children receiving age-appropriate immunization, we must do all we can to remove barriers.

Vermont predicts we will have a $54,000 shortfall in 1988, assuming we get no additional funding appropriation. We will not distribute conjugated HIB vaccine to private providers as we do with all other vaccines.

Nationally, the shortfall is predicted of $15 to $20 million in 1988.

Childhood vaccines, as everyone has stated here today, is one of the most cost effective public health activities. We are faced with a national problem needing a national solution. There are solutions:

First, provide adequate funding to cover the current vaccine and immunization program needs for the current nationwide immunization program; and

Second, head toward and embrace the concept that this should be an entitlement program for comprehensive universal immunization such as we have in Vermont that reaches the private as well as the public sector.

PREPARED STATEMENT

I request that you carefully examine the funding option. The surtax now levied on the States must be offset by additional Federal resources. Painful decisions are already beginning to be made at the State level.

Thank you for allowing State health officials to talk with you about their deep concerns about children and their immunization.

[The statement follows:]

STATEMENT OF ROBERTA R. COFFIN

Thank you for the opportunity to talk with you about the current status of the Childhood Immunization Program and the impact of the vaccine surtax on program funding.

I am Dr. Roberta R. Coffin, Commissioner of Health in the State of Vermont. I am here representing the Association of State and Territorial Health Officials. I am a Board certified pediatrician.

On July 25th, 1986, I represented ASTHO in its support of the establishment of a vaccine injury compensation program. You are to be commended for passage of Public Law 99-660, the National Childhood Vaccine Injury Act, for the purpose of creating a system to compensate children for injuries received from routine pediatric immunizations.

The passage of that law created a new system, but left it unfunded. There is no funding to cover the surtax costs. I noted this as a potential problem in 1986 in the testimony I presented at that time. It is indeed a reality. ASTHO has a high level of concern over past vaccine cost escalations and fears that the much touted leveling off of these costs is not on the horizon as believed. This makes it difficult for states to continue to immunize its children.

The increased dollars you have provided to CDC to purchase vaccines through federal contracts is laudable. However, this covers the purchase of only about one half of all public supported vaccine. Other federal funds, such as the Maternal and Child Health Block Grants, which are used by states to support vaccine costs and to insure the successful administration of a childhood immunization program at the state level have been level-funded, or slightly increased at levels less than inflation rates for seven years. This has forced states into increasing competition and demands for state and local funds, in order to keep state childhood immunization programs constant.

You perhaps remember that Congress provided a special supplemental appropriation of 20 to 25 million dollars for the purchase of DTP vaccine at the time of the original price explosion. This is an example of the infusion of significant funds which is needed now, probably on a one-time basis.

I hardly need to remind you of the current vaccine contract price for a dose of DTP. It is $9.62 purchased on federal contract. In 1987, it was 0.11/dose. This represents an increase of 8,645% per dose since 1984, and a greater than 300% increase since 1987. All states are faced with this.

The new conjugated HIB vaccine may cost $7-$8, instead of $2-3 for the older polysaccharide HIB vaccine. No increased funds have been provided for this more age-appropriate vaccine. This adds additional costs on top of the surtax problem to state health departments.

Although you may provide apparently adequate dollars to CDC, states clearly understand that these are adequate only because of a shift in many dollars previously earmarked for direct state assistance in administering vaccine programs and/or providing public health advisors, coordination of state programs, and data collection for accountability and surveillance purposes. These are all important elements if we are to continue to be sure we are immunizing all our children.

You might consider that state cost saving measures through increased efficiency could provide some needed dollars. States have already tightened their vaccine handling and purchasing programs. In Vermont, 96.5% of vaccine is accounted for and administered.

The states are worried about families who cannot afford the even greater increases in vaccine costs due to the surtax which they face when they seek routine preventive pediatric care in private physicians offices. Many families face two options: the first is to go without immunizations; the second is to seek a low-cost immunization in the public sector.

States face a big hurdle which may not peak for about six months. ASTHO is conducting a survey of the impact of the surcharge on state immunization programs. The results from 23 states which have responded so far indicate a projected shortfall of $14 million. I have attached the detail of that incomplete survey to my written testimony.

Some anecdotes shared during our state survey:

The State of Virginia has seen an increase of 15% in the growth of public clinics since January of this year. Several larger pediatric practices have office signs saying you can also get your child's immunization in a public clinic. Since November, the state has had two vaccine outages in public clinics. These clinics had to temporarily close.

The State of Colorado has a projected 1988 shortfall of $131,000, resulting in a decision to save $62,000 by not purchasing HIB conjugated vaccine. In 1985-86, they have shown an increase of 45% usage of public clinics providing DTP immunizations. This required additional state funding.

The State of Utah has passed legislation allowing a sliding fee scale to be used in public clinics. They will not provide vaccine to the private sector as they had previously.

The State of Kansas estimates a 20% growth in their public clinic attendance. A shortfall of $700,000 in their 1988 budget, however, is forcing them to curtail provision of HIB vaccine, like Colorado. It is not cost-effective to forego age-appropriate HIB vaccination.

The State of California is looking for funds to cover their increased expenditure of $1,000,000 for vaccine.

Your support of funds to CDC to purchase vaccine at the FY 87 level is likely to be inadequate because the number of children younger than six has increased each year over the past decade. In addition there appears to be an absolute growth in the number of poor and underinsured children, which heightens the need for public immunization.

Vermont has always had a generous legislature. Vermont has always provided vaccine for all children in the State, whether administered in the private or public sector. We have encouraged children to get comprehensive, preventive health care from the same individual from whom they receive acute illness care. Because Vermont, like all other states in the country, has a school entry immunization law, the vaccine should be viewed as an entitlement. If we are to prevent a decrease in the number of children receiving age-appropriate immunizations, we must do all we can to remove barriers.

Vermont predicts that we will have a $54,000 shortfall in 1988, assuming no additional funding appropriation. We will not distribute conjugated HIB vaccine to private providers as we do with all other vaccines. In addition, we may consider

1. Charging providers for all or part of the cost of the vaccine(s). (If purchasing vaccine with other than Federal grant funds).
2. Charging patients/parents a set fee for the vaccine in order to offset the budget deficit.
3. Instituting an ability-to-pay test (sliding scale) for patients.
4. Reducing the number of providers to whom vaccine is distributed (i.e. private physicians).

Choosing any of these options would have the inevitable result of reducing the percentage of children immunized in Vermont. Childhood vaccines are one of the most cost-effective, public health activities. We are faced with a national problem needing a national solution. There are solutions:

1. Provide adequate funding to cover current vaccine and immunization program needs for the current nationwide immunization program.
2. Provide Federal support through an entitlement program for comprehensive universal immunization programs such as we have here in Vermont, which reaches the private as well as the public sector.

This would enable public health department administrators and state legislators to focus on other public health priorities, instead of the demanding efforts of devising alternative schemes to manage the fiscal and immunization crises which we face today.

I request that you carefully examine the funding options. The surtax now levied on the states must be offset by additional federal resources. Painful decisions are already beginning to be made at the state level.

Thank you for allowing state health officials to share their deep concerns with you about childhood immunizations.

Association of State and Territorial Health Officials
Impact of Surcharge on State
Immunization Programs

Forty-one states, representing all regions of the country, responded to an ASTHO survey on current childhood vaccine supplies and future estimated costs resulting from the recently instituted vaccine surcharge. The following is a summary of the survey results as of Thursday, March 17, 1988.

Current Estimated Vaccine Supply*

The current estimated vaccine supply for MMR ranged from a high of 156,000 doses in California to a low of 500 doses in Rhode Island and 580 doses in Indiana. The mean responses for the MMR state vaccine supply was 20,418 doses. When asked how many months the current supply of MMR would last before the State would have to purchase at the increased price, the responses ranged from 2 weeks in Indiana and 1/2 month in Wisconsin, who have already purchased MMR at the increased price, to 15 months in Minnesota. The mean response was 5.4 months.

For DTP, the estimated vaccine supply ranged from a high of 330,000 doses in California followed by North Carolina with 259,320 and Texas with 189,255 doses, to a low of 6,500 doses in Utah. The mean response for the DTP state vaccine supply was 51,456 doses. When asked how many months the current supply of DTP would last before the State would have to purchase at the increased price the responses ranged from 1/2 month in Florida and Wisconsin, who again has already purchased DTP at the increased price, to 14 months in North Carolina. The mean response was 4.1 months.

Funds to Cover Increased Cost*

Thirty-Two states indicated they will not be receiving sufficient Federal, State or other funds to cover the increased cost of vaccines, assuming that the Federal grant award is for the amount requested. Assuming no additional funding appropriation, the approximate amount of the reporting states' 1988 shortfall based on the Federal grant request or the Federal purchase of the same number of vaccine doses in 1988 is $20,238,066. This ranges from a high of $4 million in Florida, followed by $3 million in California and $1 million in Arkansas, Arizona and Alabama to a low of $72,000 in North Dakota. Six states, Iowa, Oklahoma, Michigan, Mississippi, Pennsylvania and Minnesota reported no anticipated shortfall during the current fiscal year.

From preliminary calculations, ASTHO estimates a shortfall in federal funding to maintain the current immunization schedules among children at about $24 million. This is based upon the $18 million being transferred out of state operation funds plus approximately $6 million to meet the increased cost to states for vaccines purchased with non-federal dollars. Given the $20.2 million shortfall reported by the thirty-two states, a $24 million shortfall nationwide this fiscal year appears accurate.

Option for Continuation of Immunization Program at Present Level

The following list specifies the options available to assure continuation of the immunization program at current levels, and the number of states that are considering them:

- o Charging providers for all or part of the cost of the vaccine(s). (If purchasing vaccine with other than Federal grant funds) - 6 states
- o Charging patients/parents a set fee for the vaccine- 10 states
- o Instituting an ability-to-pay test (sliding scale) for patients - 12 states
- o Reduce the number of providers to whom the vaccine is distributed - 21 states
- o Reduce the recommended/required number of doses of DTP vaccine each child is to receive - 5 states
- o Seek additional state funding - 7 states
- o Provide DT vaccine instead of DTP vaccine
- o Decrease the types of vaccine distributed to providers - 2 states

* See attached Survey Results sheet for individual States

- Stop providing HIB vaccine - 2 states
- Direct funds from other programs - 2 states
- Institute an administrative fee - 2 states

The following are options considered by individual states:

- Provide MR vaccine instead of MMR vaccine
- Discontinue college immunization program
- Stop county health department provision of vaccine
- Cut immunization grants to local health departments
- Target persons with no financial resources
- Purchase vaccine with other federal funds which require match
- Request corporate or private donations
- Seek Medicaid funds

Charging/Collecting From Providers or Patients

Nine states indicated that their state or project area has a law/regulation/policy which restricts them from charging or collecting from providers or patients. Nineteen states do not have such a restriction.

Fifteen states already have a system in place for charging or collecting funds to defray costs. Twenty-five states do not have such a system in place at this time.

Increased Patient Load in Public Program

The single greatest source of concern beyond the $24 million shortfall in funding is the increased patient load expected in public clinics as a result of patient referrals from private practice and group health programs. There are isolated instances of such trends developing but by the summer this is expected to be a significant additional problem area for public programs. We will be happy to provide the Committee with a dollar estimate upon request.

ASTHO
State Immunization Program
Survey Results
March 1988

State	Current Estimated Vaccine Supply		Months of Current Supply		Appoximate Amount of 1988 Shortfall
	MMR	DTP	MMR	DTP	
Alabama	7,700	41,000	2	2	1,017,928
Alaska	3,000	14,000	2	2	300,000
Arizona	15,000	32,000	3	3	1,273,000
Arkansas	20,000	35,000	6	4	1,100,000
California	156,000	330,000	6	6	3,000,000
Colorado	13,209	37,530	6	6	131,812
Connecticut	22,000	21,000	5	1.5	500,000
Delaware	980	14,500	6	5	125,223
Florida	42,640	19,995	4	.5	4,000,000
Georgia	20,730	102,905	3	4	no response
Idaho	5,315	34,335	3	6	no response
Illinois	19,200	48,100	3	2.5	500,000
Indiana	540	20,310	.25	3	460,000
Iowa	2,720	17,685	3	3	0
Kentucky	13,000	36,000	4	3	490,000
Maine	6,300	37,000	3	12	436,800

State	**Current Estimated Vaccine Supply**		**Months of Current Supply**		**Appoximate Amount of 1988 Shortfall**
	MMR	**DTP**	**MMR**	**DTP**	
Maryland	19,000	30,000	12	8	202,500
Michigan	39,000		6		
Minnesota	38,000	86,000	15	10	0
Mississippi	35,000	60,000	7	6	0
Montana	10,900	11,385	10	6	134,000
Nebraska	4,031	9,735	4	2	143,705
New Hampshire	4,380	10,200	3	2	700,000
New Mexico	12,500	30,000	6	3.5	200,000
New York	32,855	105,795	6	6	700,000
North Carolina	25,863	259,320	6	14	250,000
North Dakota	1,500	1,500	2	1	72,000
Ohio	34,000	35,000	5	2	300,000
Oklahoma	26,900	104,040	12	12	0
Oregon	35,731	40,839	11	1	430,144
Pennsylvania	50,345	67,087	10	3.0	0
Rhode Island	500	12,000	1	4	200,000
South Carolina	8,000	33,000	3.5	2.5	450,000
South Dakota	16,000	19,800	12	4	140,000
Tennessee	34,230	71,725	9	4	130,000
Texas	40,910	189,255	2.5	3	no response
Utah	8,500	6,500	3	1	430,000
Washington	28,051	19,140	4.5	.9	1,000,000
West Virginia	6,057	38,790	2	3	467,520
Wisconsin	9,000	31,000	.5	.5	755,000
Wyoming	2,580	8,235	3	5	198,454

LETTER FROM D.J. MacMASTER, JR., PRESIDENT, MERCK SHARP & DOHME

The Honorable Dale Bumpers
United States Senate
229 Dirksen Senate Office Building
Washington, D.C. 20510

March 24, 1988

Dear Senator Bumpers:

During your hearing on appropriations for the Childhood Immunization Program several questions were raised about the price of MMR II, Merck's combination vaccine against measles, mumps and rubella (German measles).

Knowing of the continuing leadership you have exercised in assuring thorough protection of the nation's children against preventable diseases of childhood, I am most anxious to address the points you raised in your opening statement and some of the other questions that arose during the hearing.

Comments and testimony implied that Merck should have reduced the price of its vaccine to offset the new surcharge designed to accommodate liability costs. In fact, we made it explicitly clear throughout the discussion of the proposed legislation that Merck, in contrast to other companies, did not increase its prices with an internal liability surcharge. We wanted it to be clear that when the proposed new Federal surcharge came into being, it would be a complete pass-through to the new compensation fund and would have no bearing whatsoever on our pricing. The misunderstanding stems from the fact that other companies had rather dramatically increased their prices with the explicit explanation that they were setting up a liability protection fund. We did not, so we had no portion of our pricing to be backed out when the new Federal excise tax went into effect. Since we believed the focus of the hearing was to establish a record of price decreases resulting from the implementation of the National Childhood Vaccine Injury Act, it was our opinion, in hindsight perhaps erroneous, that we were not an appropriate party to testify.

The fact that we have no separately imposed liability surcharge should not be taken as an indication that we have no liability concerns. In fact, while pediatric vaccines accounted for only less than 5% of Merck Sharp & Dohme sales in 1987, pediatric vaccine lawsuits were almost half of our pending cases as of December 31, 1987.

Our pricing on MMR II over the years -- and the increases referred to in the hearings -- reflects the realities of working in this demanding and costly field. Since its introduction some years ago, our unit sales of MMR have declined as the broader population has become immunized, yet the basic costs of our vaccine business and specifically our vaccine research costs have continued to rise.

Possibly the most significant factor is our continued and increasing commitment to research. Merck research has a long record of developing new vaccines, but beyond this the company continues to make improvements on its vaccines. For instance, each of the individual antigens contained in the MMR II vaccine has been improved at least once since its original marketing and the combination itself is a second generation vaccine. In addition, in the area of adult vaccines we improved our original pneumococcal pneumonia vaccine and developed a recombinant version of our hepatitis B vaccine, the first genetically engineered vaccine for human use to be licensed anywhere in the world. We are engaged in clinical trials on a conjugate Haemophilus influenza type B vaccine which will be particularly important for infants who are at the greatest risk from meningitis and a significant improvement over currently marketed vaccines which are not recommended for children under two years of age. Development of a chickenpox vaccine has been ongoing for more than twenty-five years, and we have made a substantial investment of resources toward the discovery of a vaccine against the AIDS virus, a project which may not result in a successful product until well into the next century, if ever.

In light of the many factors affecting our business, we believe our pricing has been sound. The value delivered is exceptional. MMR II is the least expensive of the pediatric immunizations that were reviewed at the hearing. Even without the liability surcharge the price of DPT vaccine increased 900% between 1982 and 1987 in the private sector and 1500% in the public sector. Had the price of MMR increased commensurately, the price of MMR in 1987 to the public sector would have been $64.05 per dose and to the private sector $104.40 per dose. In the public sector, including the excise tax, full immunization with MMR II is only $16.18, compared with a total cost for DPT of $48.10. On a single antigen basis, MMR II at $5.39 per antigen costs less than OPV at a cost of $5.44.

To provide expected lifetime protection for our children at these nominal costs is remarkable, and I do hope that as the Subcommittee continues to review the situation it will conclude that our vaccine contributions to national health remain an outstanding service and value.

Sincerely,

Senator BUMPERS. Dr. Coffin, thank you very much.

We have another rollcall vote which will take about 5 minutes of my time to go over and come back.

Dr. Narkewicz, I do not want you to start and have to interrupt you in the middle of your testimony, so I will be back shortly. Then I have a few questions for all of you.

[A brief recess was taken.]

Senator BUMPERS. Dr. Narkewicz, we finally get to you.

STATEMENT OF DR. RICHARD M. NARKEWICZ

Dr. NARKEWICZ. Mr. Chairman, thank you. I am Dr. Dick Narkewicz, president of the American Academy of Pediatrics, and I am a practicing pediatrician in Vermont.

I appreciate your cooperation in letting us change the schedule a little bit. We felt in the presentation it was important to present the demographics of the problem and the impact on the State before we started discussing the plight of the young families trying to immunize their children against the preventable childhood illnesses and the cost crisis facing them in our Nation.

I commend you, Mr. Chairman, for calling this hearing at this time, because emphasizing cost factors is critical, since we have addressed the liability issues. You have been the leader in this, and it is with your support that this program exists and is in operation today.

You stated in your initial statement in the 1930's and 1940's, diphtheria, pertussis, tetanus, measles, mumps, and rubella were rampant killers and cripplers of this Nation's children. Now, most of us do not remember the thousands of deaths, the clang of the iron lung, or the wards of paralyzed patients, or the gasp of a young child, usually an infant, dying of pertussis, common whooping cough.

Senator BUMPERS. The immunization program is a balancing act. We all understand that, but most pediatricians in this county, the professionals whom I have to depend on, say there is just no question about what is right for the children of this country.

Please go ahead.

Dr. NARKEWICZ. Absolutely no question. You are correct. But not only does the public not know about that, but many of the young pediatricians that I practice with and certainly the young residents that I have come to my office, because I do teach part time, have never seen it, nor hopefully, if this program works well, will they ever have to see it.

With the advent of the adequate vaccines, though, there has developed a cooperative effort between the private sector and the public sector that is a stunning success by any measurement, medical, economic, political, in protecting the millions of children against the common preventable diseases of the young.

You and your members of the committee are well aware of the long, arduous battle we fought to keep the immunization system viable. The academy, along with the majority of the public health groups which are represented here today, two of the three manufacturers of childhood vaccines, believe that the vaccine compensation legislation enacted by Congress will effectively address the liability issue, which in the recent years has been the major force driving the cost of vaccines.

However, today, we face a cost crisis that demands immediate attention. The numbers themselves tell the story, and you told it. Prior to the enactment of the vaccine compensation legislation, the cost of DTP vaccine increased 5,000 percent, the cost of oral polio 200 percent, and the cost of MMR 165 percent in those years of 1982–87 that you mentioned.

Now, with the legislation came the economic reality that a surcharge would be necessary to pay for the compensation fund. To keep that surcharge at a minimum, it also became necessary to obtain funds from the general revenues to take care of the older vaccine injury cases.

On the first of January, the new vaccine tax became effective. On that date, Mr. Chairman, the DPT vaccine increased 25 percent, oral polio decreased 5 percent, and MMR increased 51 percent.

Mr. Chairman, logic escapes me here. While we do, indeed, recognize that the manufacturers will need some proof of experience with the compensation to assure them that it will substantially relieve their liability concerns, we do not believe these higher costs can be justified.

These costs are placed on the backs of consumers in the private sector and in the public sector have a devastating impact on Federal and State budgets.

Let me give you an example. For a child to be completely immunized for school entry in the private sector, the vaccine costs alone are $117.06, while in the public sector that cost is still a staggering $69.72. Purchasers of vaccines are usually younger parents, who are just as price sensitive, maybe even more so, as other consumers.

Discouraging immunizations by making them cost prohibitive is as detrimental to a strong immunization program as is an insufficient supply.

I also have a fear that this cost differential may drive many parents into the public sector for free vaccines. Come this fall, instead of the traditional 50–50 public/private share when all the kids are coming to get their preschool immunization, we may be looking at as many as 70 percent of children turning to the public clinics for their immunizations, where they are free of charge.

We see three primary situations where children will be shifted over to the free public sector, which we realize is truly not free, and that is the Medicaid patient whose physician cannot afford the low reimbursement versus the high cost of the vaccine that they are paying; the parents who simply cannot pay for their visit have to make a choice between the vaccine and the visit; and the HMO's who have not budgeted for that large increase.

This shift, or dumping as I would like to say, of the children into the public sector is occurring in State systems that are only budgeted and underbudgeted to take care of 50 percent of the child population. Remember, no provisions have been made for any increased caseload or for the additional personnel that would be required.

Now, to further complicate this situation, all this is occurring when our immunization rates are already down, particularly in preschool children.

I would like to emphasize something that was said in previous testimony. Specially alarming are the poor rates among the 2 year olds, because if you understand these diseases, they indeed are the ones that are most susceptible to death and to disability and to illness from these preventable illnesses.

Congress has addressed the liability crisis. We are now facing a cost crisis, and if immediate action is not taken our Nation may be facing a crisis of disease, an unnecessary rise in preventable diseases in children.

The January 1 tax will not only have an impact on the fiscal year 1989 budget, it also impacts immediately on the current budget. We feel that such sums clearly fall under the urgency of supplemental funds and urge you to include such sums as necessary to assist States in purchasing at least the same amount of vaccine as they did last year. We calculate this number to be in the range of $20 million.

Following the same logic, our request for fiscal year 1989 is an additional $34.7 million for the immunization program. This amount restores to last year's level moneys for State operations and the vaccine stockpile and would assist the States with the purchase of the new and improved PRP-D, the HIB vaccines.

This request is only for the traditional 50 percent Federal market share and really does not allow for the anticipated increase.

In addition to these necessary funds for the immunization program, it is also critical that Congress fully fund the amount authorized for the retroactive vaccine injury cases. If Congress compromises on the amount allocated to this line item, there would be little incentive for the companies to reduce their liability costs for the next several years.

Now that I have reviewed the hard numbers, Mr. Chairman, let me turn to the cost crisis we must address ourselves to today.

Given the potential for significant patient shifting this fall, we must take steps to avert that problem. Several States have taken action in an effort to minimize the impact of price increases in the private sector.

You have heard from the State of Vermont, which I am privileged to practice in and is under the leadership of a fine and dedicated pediatrician. Such a model is a model for any program.

In the State of Oregon, the State Health Department has designed a plan whereby Federal funds other than those earmarked by Congress for public programs under section 317 of the Public Health Services Act are initially used to purchase vaccine for the private sector providers.

In turn, a grant from these providers would be pooled to repay these amounts. In this way, a considerable savings in vaccine costs passed on to the parents can be achieved without expending additional Federal dollars.

A third option might be for the Federal Government to increase its support of the childhood immunization program to assist States with the extra caseload.

For the record and for your future consideration, we would also like to put on the table the idea of a Federal consolidated purchase for all vaccines for all children. This essentially would expand the Vermont model for all States. There would be no barriers in this country to the complete immunization of all children.

Mr. Chairman, we also recommend immediate dialog between the Congress, CDC, manufacturers, and the health organizations such as our academy of pediatrics to resolve this cost crisis.

We believe that the Oregon and Vermont models should serve as a potential model for a cooperative Federal/State program whereby most vaccine is purchased by the Federal Government on behalf of both public and private programs and distributed through the States.

In this way, transactional costs such as shipping and detailing can be stripped from the price to private providers. We believe price discrepancies based on factors other than transactional costs are inappropriate.

The childhood immunization program exemplifies the best cooperative efforts among Federal, State, and local government and medicine's private sector. It is time for industry to review its role in this process and to assume its responsibility to exercise fiscal constraint in pricing of the vaccines.

PREPARED STATEMENT

We all share the common goal of protecting our children. The economics of the situation places our ability to do so in jeopardy. It is with our children in mind that we must work together toward some extraordinary options in meeting their needs.

Thank you, Mr. Chairman.

[The statement follows:]

STATEMENT OF RICHARD M. MARKEWICZ

Mr. Chairman, members of the Committee, I am Dr. Richard Markewicz, President of the American Academy of Pediatrics. I commend you Mr. Chairman for calling these hearings today on an issue of critical importance to our nation's children. You have been the stalwart watchdog over the childhood immunization program for many years and it has been your support and that of your colleagues here today that have kept that program in operation.

The federal immunization program by virtually all medical, economic and political measures is a stunning success story in protecting millions of children against common preventable infectious diseases. The past successes of this program exemplify the best cooperative efforts among federal, state and local governments and medicine's private sector. As you know, in recent years this program came under a legal cloud that threatened its stability, slowed the development of new vaccines and sent vaccine prices soaring. Our national immunization program was placed in jeopardy due to increased costs of liability coverage for vaccine manufacturers. Congress has addressed the liability crisis under PL99-660 and PL100-203, and we believe that over the long term the system will be far better off. However, today we are facing a crisis of another kind. Today we face a cost crisis that demands immediate attention.

The vaccine compensation program was enacted in the midst of and partly as a reaction to skyrocketing vaccine prices. The numbers themselves tell the story. Prior to the enactment of the vaccine compensation legislation, the cost of DTP vaccine increased 5000% between the years of 1982 and 1987. The cost of OPV increased 200% and the cost of MMR increased 165%. The Academy, along with the majority of the public health groups and two of the three manufacturers of childhood vaccines, believe that the vaccine compensation legislation enacted by Congress will effectively address the liability issue which has been the major force driving up the cost of vaccines. However, with the good done by that legislation came the economic reality that a surcharge would be necessary to pay for the compensation fund. To keep that surcharge at a minimum, it also became necessary to obtain funds from general revenues to take care of the older vaccine injury cases.

On January 1, 1988 the new vaccine tax became effective. And on that date, DTP vaccine increased 25%; OPV decreased 5%; and MMR increased 51%. Mr. Chairman, logic escapes me here. While I do indeed recognize that the manufacturers will need some proof of experience with the compensation system to rest assured that it will substantially relieve their liability concerns, we do not believe these higher costs can be justified. Nor do we feel that all liability costs should be placed on the backs of the consumer. Since 50% of these vaccines are purchased and administered through the public sector, these cost increases are having a devastating impact on federal and state budgets. For the remaining 50% of children in the private sector, these increased costs are for the most part coming out of parents' pockets, because routine vaccines are not traditionally covered by insurance. And while the percentage of cost increases has been similar, the actual cost of vaccines is considerably higher resulting in extremely heavy burden on parents (see Table 1 & Table 2).

Let me give you an example. For a child to be completely immunized for school entry (5 DTP, 4 OPV and 1 MMR) in the private sector, the vaccine costs alone are $117.06. In the public sector, that cost is $69.72. Purchasers of vaccines -- usually younger parents -- are just as price sensitive, maybe even more so, as other consumers. Discouraging immunizations by making them cost prohibitive is as detrimental to a strong immunization program as is an insufficient supply.

Mr. Chairman, I also fear the cost issue will break down the traditional public/private share in the immunization process. While we don't have firm data, many of our members tell us they can no longer afford to give immunizations in their offices. Inventory supplies are simply too costly and many of their patients cannot pay these high costs which are usually in conjunction with a regular office check-up. Come this Fall, instead of the traditional 50/50 public/private share, we may be looking at as many as 70% of children turning to the public clinics for their immunizations where they are free of charge. We see three primary situations where children will be shifted over to "free" public sector immunizations:

1. Medicaid-eligible children that were receiving immunizations from private physicians may be referred to public clinics because private doctors will not be able to shoulder the burden of increased vaccine costs compared to low reimbursement rates.

2. Many parents who cannot afford these out of pocket costs will simply choose to go to public clinics on their own.

3. And HMO's who did not anticipate these increased costs may recommend that patients go their clients going to the public side for immunizations.

This shift (or dumping) of children into the public sector is a shift into a system that is only budgeted (and underbudgeted, I should add) to take care of 50% of the child population. No provisions have been made for an increased caseload or for the additional personnel that would be required.

To further complicate this situation, all this is occurring when our immunization rates are already down, particularly in our preschool children. In 1980, 22.3 percent of children aged 1-4 years were not fully immunized against polio. In 1985, 24.3 percent of the same age group had not been immunized. In 1980, 22.5 percent of the same under four age group were not immunized against rubella. In 1985, that percentage rose to 24.5 percent. Scariest of all -- although reported cases of measles and mumps have declined since 1980, the number of reported pertussis cases has increased almost 3-fold -- from 1,730 in 1980 to 3,589 in 1985.

After a record low of 1,497 measles cases in 1983, the number of measles cases increased each year through 1986. While the preliminary data from 1987 indicate a reduction in measles cases, high costs of vaccines combined with inadequate federal/state funding support will lead to an increase in unvaccinated preschoolers. No one can quantify the pain associated with those diseases to the child and to his or her family, but when the capacity to prevent these conditions is at hand, failure to protect our children is doubly cruel.

As I stated previously, Congress has addressed the liability crisis. We are now facing a cost crisis, and if immediate action is not taken, our nation may be facing a crisis of disease -- an unnecessary rise in preventable disease in children.

The January 1 tax will not only have an impact on the fiscal 1989 budget, it also impacts immediately on the current budget. We feel that such sums clearly fall under the urgency of supplemental funds and urge you to include such sums as necessary to assist states in purchasing at least the same amount of vaccine as they did last year. We calculate this number to be $20 million.

Following the same logic, our request for fiscal 1989 is as follows:

	FY'88 APPROPRIATION	FY'89 ADMINISTRATION REQUEST	AAP REQUEST
GRANTS TO STATES	$86m*	$93m**	$111m
SURVEILLANCE	$ 8m	$ 8m	$ 8m
STOCKPILE	$ 4m	$ --	$5.12m
VACCINE PROGRAM	--	$.5m	$ .5m
HiB VACCINE	--	--	$ 12m***
TOTAL	$98m	$102.5m	$136.12m
RETROACTIVE VACCINE INJURY CASES	--	--	$ 80m

*Includes $18.5 million for state operation costs
**Excludes all monies for state operation costs
***Covers new HiB vaccine (PRP-D).

Grants to states are used by state and local health agencies to plan, develop and conduct programs to immunize children against measles, mumps, rubella, polio, diphtheria, tetanus and pertussis. Costs for these basic vaccines have increased by 28% since the last fiscal year. States have also used these grant monies to purchase the HiB vaccine, which is effective in preventing the most common cause of bacterial meningitis in children. A new and improved vaccine is now available, PRP-D, effectively removing the older vaccine from the market. With improvement also comes an increase in price. An additional $12 million will be needed to purchase this vaccine. Monies to assist states with program operations are also included in these grants, but these monies have been eliminated in the Administration's budget request. These state operation funds are essential to the running of the vaccine programs. Hence, the Academy recommends an figure of $111 million for grants to states and $12 million for the purchase of the PRP-D vaccine. This request simply allows the federal government to purchase the same amount of vaccine as they did last year and restores the program operation costs to the '88 level.

We support the Administration's request of $8 million for surveillance activities, research and technical assistance.

We do not agree with the Administration's elimination of monies for the vaccine stockpile. The CDC has testified on several occasions that this country needs a six-month stockpile of vaccines to meet our national needs. With a single producer of both MMR and OPV vaccines and only two producers of DTP vaccine, stockpile is simple insurance against any interruption in vaccine supply. Such an interruption could be a fire, strike or production problem. We currently have on hand a little better than a three-month supply of these vaccines. The Academy recommends that funding be extended at the fiscal '88 level and have included the vaccine tax on this amount, bringing the total to $5.12 million.

We support the request of $.5 million for the Vaccine Program. We are concerned, however, that no funds have been requested to administer the vaccine compensation legislation. The new law requires that educational materials be developed, severe reactions be reported and a Commission be established. Unless the Department has set aside funds for these purposes, the implementation of this program could be delayed. In this instance, delay is costly. And the cost would be paid for by children who have been inadvertently injured by vaccines as well as those who might not be immunized at all because of continuing high costs.

In addition to these necessary funds for the immunization program, it is also critical that Congress fully fund the amount authorized for the retroactive vaccine injury cases. Congress must send a strong signal to parents that there is a secure compensation fund available to assist their children and to manufacturers that Congress has assumed some responsibility for vaccine injuries described as no fault in the vaccine injury table contained in the legislation. Without the appropriation of the full $80 million, parents will have no alternative but to pursue a lengthy tort remedy for alleged vaccine injuries and companies will perceive inadequate relief from pending litigation (the major factor in vaccine costs). For Congress to compromise of the amount allocated to this line item, there would be little incentive for companies to reduce their liability costs for the next several years.

Now that I have reviewed the "hard" numbers, let me turn to the cost crisis we must address ourselves to today. Given the potential for significant patient shifting (or dumping) this Fall, we must take steps to avert that problem.

Several states have taken action in an effort to minimize the impact of price increases in the private sector. One such model is from the state of Oregon. The state health department has designed a plan whereby federal funds, other than those earmarked by Congress for public programs under section 317 of the Public Health Services Act, are initially used to purchase vaccine for private sector providers. In turn, a "grant" from these providers would be pooled to repay these amounts. In this way, a considerable savings in vaccine cost can be achieved without expending additional federal dollars. No changes would be required in existing law to facilitate this purchase agreement, although it would require the cooperation of the vaccine manufacturers. And in our judgment, an agreement must be reached that the cost of these vaccines to the public sector would not be increased, should other states elect to go this route.

Another model is that of my home state, Vermont, and other smaller states including Maine and North Dakota. In these states, all vaccine is purchased by the state and given to all providers free of charge. This arrangement goes a long way toward assuring that all children are immunized, but it does require a significant committment of state dollars up front. For many states, this model may not one that can be pursued at this point in their fiscal year.

A third option would be for the federal government to increase its support of the childhood immunization program to assist states with the extra caseload. This would require a supplemental appropriation of an additional $20 million over and above the amount requested.

And for the record and for your future consideration, we would put on the table the idea of a federal consolidated purchase for all vaccines for all children. This essentially would expand the Vermont model for all states. There should be no barriers in this country to the complete immunization of all children.

Mr. Chairman, we recommend immediate dialogue between the CDC, manufacturers and health organizations such as the Academy to resolve this cost crisis. We believe that the Oregon and Vermont programs should serve as potential models for a cooperative federal-state program whereby most vaccine is purchased by the federal government on behalf of both public and private programs, and distributed through the states. In this way, transactional costs such as shipping and detailing, can be stripped from the price to private providers. We believe price discrepancies based on factors other than transactional costs are inappropriate.

As I mentioned in the beginning of my testimony, the childhood immunization program exemplifies the best of cooperative efforts among federal, state and local governments and medicine's private sector. It is time for industry to review its role in this process and to assume its responsibility to exercise fiscal constraint in the pricing of vaccines. We all share the same goal of protecting our children. The economics of the situation places our ability to do so in jeopardy. It is with our children in mind that we must now work together toward some "extraordinary" options in meeting their needs.

TABLE 1

PRICES ($) PER DOSE OF CHILDHOOD VACCINES IN THE PRIVATE AND PUBLIC SECTORS 1982 and 1987

	PRIVATE SECTOR			PUBLIC SECTOR		
VACCINE	1982	1987	1988*	1982	1987	1988*
DPT	$ 0.37	$ 8.92	$11.03	$ 0.15	$ 7.69	$ 9.62
OPV	$ 2.75	$ 8.67	$ 8.67	$ 0.48	$ 1.43	$ 1.36
MMR	$10.44	$20.72	$27.23	$ 4.02	$10.67	$16.18

TABLE 2

COST FOR FULLY IMMUNIZING A CHILD IN THE PRIVATE AND PUBLIC SECTORS 1982 and 1987

	PRIVATE SECTOR			PUBLIC SECTOR		
VACCINE	1982	1987	1988*	1982	1987	1988*
5 DPT	$ 1.85	$44.60	$55.15	$ 0.75	$38.45	$48.10
4 OPV	$11.00	$34.68	$34.68	$ 1.92	$ 5.72	$ 5.44
1 MMR	$10.44	$20.72	$27.23	$ 4.02	$10.67	$16.18
	$23.29	$100.00	$117.06	$ 6.69	$54.84	$69.72

*Costs reflect vaccine surcharge under P.L. 100-203

Senator BUMPERS. Thank you, Dr. Narkewicz and Kay and Dr. Coffin. Thank you all for really fine and thoughtful statements. I hardly know where to begin with this.

Dr. Narkewicz, let me start with just this simple question.

Does a company like Lederle sell directly to doctors, or do they also sell to the druggists? Do druggists maintain an inventory of these vaccines?

Dr. NARKEWICZ. I cannot speak for everywhere, Senator Bumpers, but the majority of the physicians buy it directly from the companies.

Senator BUMPERS. Why do we have this big difference between the public and private price?

Dr. NARKEWICZ. I wish I knew the total answer to that. Physicians purchase it in small quantities. They have detail persons come into the office, whereas the Federal or State purchases it in bulk.

We are told when we meet with the manufacturers that we are passing on research and developing costs which are appropriate to be passed on to the private sector.

We do acknowledge a feeling that those who come to the private sector are more capable of paying for services; however, when you look at it critically you will find that the majority of the vaccine costs are paid for out of the pocket of young patients who are not affluent. They are not the affluent population that comes to see the pediatrician.

Aside from that, I really cannot understand, for instance, why the price of oral polio is roughly eight times higher and the MMR is almost double the cost in the public sector. It defines my logic a little bit.

Senator BUMPERS. Maybe we ought to let CDC do all the vaccine procurement for all the States. We could save millions of dollars that way, could we not?

Dr. NARKEWICZ. Well, we could if we had some guarantee that the price of all the vaccines would not go up accordingly.

Right now, they maintain quite a difference in price like this. If I could sincerely believe that it would go down like this, I would agree with you, but I have the feeling it might go like this.

Senator BUMPERS. Well, based on our experience here, there certainly is that tendency. If we were going to do that, I would expect even the public cost to go down. If all the manufacturer would have to do is manufacture the vaccine and ship it to one central purchaser, they would eliminate an awful lot of overhead costs.

Dr. Coffin, describe for me exactly how it works in Vermont. I am not sure I understand it.

Dr. COFFIN. Basically, we purchase our vaccine both on Federal contract and stockpile it in a central location.

Senator BUMPERS. Incidentally, how long does this vaccine keep?

Dr. COFFIN. It varies, depending on the——

Senator BUMPERS. How about DTP?

Dr. COFFIN. DTP, 2 years.

Senator BUMPERS. How about MMR?

Dr. COFFIN. One year and eighteen months.

Senator BUMPERS. Go ahead.

Dr. COFFIN. We then distribute it out through our 11 district offices locally throughout the State. Doctors and clinics then come to the office or arrange for a pickup at 1 of those 11 district offices. It is a very tight system. There is not a dose that escapes our notice, I really firmly believe.

We are able to make sure that the shipments are properly refrigerated, are protected——

Senator BUMPERS. Do these vaccines all require refrigeration?

Dr. COFFIN. It varies. Some of them require freezing, some of them do not require freezing but refrigeration. Some of them need reconstituting, and so forth. So that it varies, and the handling of the vaccine itself is a science. It is something that we carefully work with our own staff in but then also instruct and work with the local providers, physicians and so forth.

It is a relatively easy system once it is set up and, as you say, it certainly would be economies of scale without any questions, I would believe.

Senator BUMPERS. You buy under Federal contract, but I assume that they ship from the manufacturers directly to you?

Dr. COFFIN. Yes.

Senator BUMPERS. Then you have facilities to keep significant quantities of these vaccines?

Dr. COFFIN. Right. We stockpile it in one place and then distribute it in the 11 different sites and stockpile it some locally there. We are able to redistribute it. For instance, when we see that there is an outdated supply that is not being used, we know that. We are able to shift it to a physician who is using it more rapidly for something.

These are things that can be done so that we use every ounce of it.

Senator BUMPERS. That sounds like an efficient system for everybody. You are convinced that Vermont saves a lot of money doing this, are you not?

Dr. COFFIN. It saves a lot of money, but it is also spending a lot of money if you look at it in absolute dollars. We are spending a lot more than we used to, and we now are spending more State dollars than we are spending Federal dollars. So we need relief.

Senator BUMPERS. Dr. Narkewicz, have we ever reached a 6-month stockpile in these vaccines?

Dr. NARKEWICZ. Not to my knowledge, and I think it is extremely important.

Senator BUMPERS. We are not going to reach the 6-month mark unless we put more money in this, are we?

Dr. NARKEWICZ. No; the administration's request does not include this. Our specific request which was appended to our written has asked that we put $5.12 million in.

I really think that we need to develop a 6-month stockpile. It was not that long ago that there was a batch problem with one of the DTP's. I can recall it vividly because we at the academy had to send out an urgent request to all of the pediatricians to alter their immunization practices.

First, we were just going to immunize the very young. We were going to skip the booster shot at 18 months. We were even talking about reducing the amount of vaccine that we gave, and we know that it is inappropriate. It is not adequate.

But should we get into difficulty and with two manufacturers now and certainly with oral polio and MMR only being one manufacturer, that is a serious concern for this country, because you heard Dr. Hinman say there is no way they can pass the flag and crank up the system.

I think people think if the manufacturers stop, the Government is just going to step in and do it. That could not be farther from the truth. It just cannot be simply done. We have to have the stockpile.

Senator BUMPERS. You consider that a critical item?

Dr. NARKEWICZ. I certainly do.

Senator BUMPERS. I was just looking at some figures on our stockpile. We have a 17-week supply of IPV, 21 of OPV, 21 of MMR, and 15 of DTP. So it would take several million dollars, of course, to get all those up to a 6-month stockpile level.

Dr. Coffin, do you have any figures to tell us what a proposal for making immunization an entitlement would be?

Dr. COFFIN. I could supply them for you.

Senator BUMPERS. Would you do that?

Dr. COFFIN. I would be happy to work on that with CDC. I would be happy to.

Senator BUMPERS. Kay, do you have any thoughts on that?

Ms. JOHNSON. I have some thoughts on it, but I also could not supply you with a number this afternoon.

Senator BUMPERS. Dr. Coffin, let me ask you this question. You have hit on the fact that our most significant problem in immunizing preschool children is reaching those in the inner cities.

Are children in those areas suffering outbreaks of some of these diseases because pools of unimmunized children develop?

Dr. COFFIN. Certainly that is true. I think Dr. Hinman really has that detail as best as anyone.

Senator BUMPERS. Dr. Hinman, the question was regarding the inner cities and the fact that a large number of minority children in the inner cities, are not being immunized.

Do the statistics on instances of these disease also bear out that those areas are the ones who are being inflicted with the disease?

Did I make that question clear?

Dr. HINMAN. Mr. Chairman, I think measles is a very efficient way of detecting areas where immunization levels are not high.

Senator BUMPERS. In other words, when you see an outbreak you know something is wrong there in terms of immunization levels?

Dr. HINMAN. There are two possibilities. One is that there have been vaccine failures, and this is the situation we often see in school outbreaks. The other is in preschoolers. It is primarily an indication of nonvaccination.

I believe Ms. Johnson mentioned that something on the order of 80 percent of the cases of measles occurring in children 16 months to 4 years ago were what we consider preventable cases; that is, occurred in children who should have been vaccinated but were not, had not been.

Senator BUMPERS. Two or three years ago some college had outbreaks of measles.

Dr. COFFIN. I will speak to that. That was Dartmouth College, next door to Vermont.

Senator BUMPERS. It was Dartmouth.

Dr. COFFIN. We had quite an outbreak in Vermont.

Senator BUMPERS. The University of Arkansas had an outbreak the same year.

Tell me about Dartmouth. Now, Dartmouth is a fairly cosmopolitan school with students attending from all over the United States. Why was there a measles outbreak there?

Dr. COFFIN. Well, their college age was just at the age when the introduction of the measles vaccine was problematic. Either kids at that age did not get it, they got it early, they got it before 12 months of age, or they got the wrong kind of vaccine. They did not get the fully protective measles vaccine. So all those things were working against us at that time.

Now there is another factor, too, and that is that colleges by and large still do not have good strong immunization admission policies. Some of them do. We in State programs have been working to make sure that colleges do have those kind of programs in place, but many colleges still do not. They are not nearly as good as the kindergarten or first grade childhood entry programs into schools.

So that both those things were working against us at that time. Things are better but still not ideal.

Let me just briefly go on and say that one of the things the States told me when we were conducting the survey they were considering doing was ceasing the efforts at trying to get college immunization entry programs in place. They were considering giving DT instead of DTP. They were considering giving MR instead of MMR, all these kind of things that really do not provide for long-term security.

Senator BUMPERS. Betty gets a publication from HHS, I think, once a week, maybe once a month. What is that called, MMR?

Dr. COFFIN. MMWR.

Senator BUMPERS. When I look and see these sudden increases in, say, measles or mumps and you look down the list of States, you will invariably find that one or two States are responsible for that big increase.

Does that mean that that State has just not been doing its work in its immunization program? What does that normally reflect?

Dr. Coffin. I think it sometimes reflects that, but it many times has many, many variables working at it. Certainly, the problem that I cited about the college problem, and I think Dr. Hinman should perhaps talk about this a little more than I, the problems with whether we should give booster measles vaccine, the problem of immunization dose versus immune response and so forth are all things that we totally have not worked out 100 percent.

Dr. Hinman may want to add to that.

Senator Bumpers. Do you have anything to add to that, Dr. Hinman?

Dr. Hinman. Senator, I would just say that, for example, with mumps, in the last couple of years the largest outbreaks we have seen have been in States which have not had a very aggressive approach to mumps immunization. Specifically, for example, Illinois, which had more than 1,000 cases of mumps, as I recall, did not include mumps immunization in their school immunization requirement. It does now as a result of the major outbreak.

Senator Bumpers. They had to have it explained to them, did they not?

Dr. Hinman. Well, mumps is not quite as contagious as measles, but it also can seek out susceptibles.

Senator Bumpers. Finally, Dr. Narkewicz, let me just ask you this. You said that these prices could not be justified.

Let me say this. I thought that Mr. Johnson made a fairly plausible case for leaving an internal surcharge on the DTP vaccine in place. Still, there is something wrong when we pass a vaccine compensation bill and the cost of everything is going to go up even with that system.

In the case of Merck, they have actually increased the price of their vaccine. They have increased the price of their vaccine plus the surcharge. Now that really does not make any sense to me.

Dr. Narkewicz. It makes no sense to me, either. In just sort of a homemade way, I understand a little bit what industry is doing.

When we passed the vaccine compensation legislation, the surcharge was based on the fact that 100 percent of all the people would go through the compensation system.

In talking with the manufacturers, and you put your finger on it this afternoon, they said we do not believe that everybody will go through. The figure I quote is they only believe that maybe 40 percent will go through. So they, in turn collect internal liability for a perceived amount of 60 percent of what they have.

That may be so, but the unfortunate outcome of that is that therefore, 160 percent of the liability is passed on to you and I as the consumer at this point, and that just does not seem right at the present time.

There is another factor involved here, too, which is kind of a subtlety. The law says specifically that you have to go through the compensation system and either accept an award and then you do not sue, or if you do not accept an award you sue.

If you think about it a little bit, we are collecting the surcharge right now. On October 1, anybody who wishes to sue will first have to go through the compensation system. In order to qualify, they have to have something that is long term; that is, at least 6 months. So we will have to wait at least 6 months before they can say whether that award qualifies. Then the system has up to 1 year before it awards anything.

It sounds to me like everybody is going to get an 18-month free ride during that period of time. The question I would have is what are they going to do with the internal liability that they collect?

From our calculations, if it is true that there are about 19 millions of DTP each year, and they said they put this on in 1986, they are not the only company that is doing this. We calculate that there must be about $233 million floating around out there.

If things look a lot better, are they going to rebate that money to all those poor parents who had to pay the internal liability charge on that? What is going to happen?

We have a lot of unanswered questions on that. Why at this point do they really need to pass on those liability costs when in place is a system which is effectively designed to control it?

Senator BUMPERS. You know, Doctor, I started to ask Mr. Johnson what Lederle plans to do with any of the internal surcharge that turned out to be excess.

Incidentally, the Government has paid a lion's share of the Federal vaccine surcharge, and the taxpayers have paid a good big lion's share of that, too.

Dr. NARKEWICZ. 50 percent.

Senator BUMPERS. Yes; 50 percent.

So I started to ask him this afternoon, but I knew that would be too conjectural at this stage of the game. Still, I would like to know.

ADDITIONAL SUBMITTED STATEMENT

The subcommittee has received a statement from David J. Williams of Connaught Laboratories, Inc., which we will insert in the record at this point.

[The statement follows:]

STATEMENT OF DAVID J. WILLIAMS, PRESIDENT, CONNAUGHT LABORATORIES, INC.

I appreciate the opportunity to present this statement on behalf of Connaught Laboratories, Inc. (CLI) for the record of the hearing of March 15, 1988 before the United States Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Committee on Appropriations.

Connaught Laboratories, Inc. and its parent company, Connaught Laboratories Ltd., of Toronto, Canada, have as their principal focus the production of vaccines for pediatric use. Our products prevent childhood diseases such as diphtheria, tetanus, pertussis, polio, and Haemophilus influenzae type B, among others. At our headquarters in Swiftwater, Pennsylvania, more than 500 employees are engaged in the research, development and manufacture and marketing of vaccines and biological products.

Challenges to Immunization

Because of our commitment to providing quality vaccines, we would like to contribute our perspective on the current state of the nation's immunization enterprise, which is perhaps the most remarkable public health success story of this century. That success appears to be threatened, however. There are serious signs that challenges are developing that could endanger our ability to prevent disease in young children. We have already seen decreased levels of immunization and outbreaks of diseases that we are capable of preventing. A substantive commitment on the part of all of us involved in prevention will be necessary to develop long-term solutions to these emerging problems.

Current Funding Dilemmas

One factor in the decline in immunization, particularly among pre-school children, appears to be the inadequacy of appropriations for state and local immunization programs. This state and local funding shortfall can be attributed to two primary sources: escalating vaccines prices due to product liability claims, and the assessment of excise taxes on doses of Diphtheria, Tetanus and Pertussis (DTP), Measles, Mumps and Rubella (MMR) and polio vaccines as a result of the National Childhood Vaccine Injury Act of 1986. Although the costs of the vaccine to public health departments have risen, their appropriations have not kept pace. In addition, there is currently a critical need to resupply federal vaccine stockpiles, which will make the problem become even more acute.

CLI advocates increased federal appropriations to compensate for these shortfalls and to avoid further erosion of our ability to prevent diseases in the thousands of babies who need this protection.

One important step has already been taken — the enactment of the National Childhood Vaccine Injury Compensation Program. Yet there are essential elements of the program still unresolved, which will require additional funding. When the Act was funded by the Omnibus Budget Reconciliation Act of 1987, only prospective vaccine-related injury claims were to be paid out of the pool established from vaccine excise taxes. Compensation for claims based on injuries occurring prior to October 1, 1988 was to be provided by an appropriation from general revenues.

The need to fund these retroactive claims will place still more pressure on the limited resources currently allocated for immunization.

Compensation Act's Affect on Vaccine Pricing

Many believed that the passage of the Act would, in effect, have reduced vaccine prices immediately. To some degree, this has taken place. CLI decreased its basic catalogue price for DTP by more than 30 percent after passage of the funding mechanism. The decrease reflects our estimate of the degree to which product liability exposure, including legal defense costs, will be reduced as a result of the compensation system. However, when the excise tax was added to that figure, the overall cost of the vaccine increased.

CLI actively supported the Vaccine Compensation Act despite our stated concerns about its potential for increasing vaccine prices. We did so because we felt that it was essential for a program to be enacted for those children who needed help quickly. In addition, it was —and is— our expectation that, at a minimum, the Act would meet one of its critical objectives: stability of supply.

However, the continued ability of claimants to enter the tort system should they be dissatisfied with the compensation awarded under the system, results in continuing liability exposure for the company. There is no requirement that those who were vaccinated before October 1, 1988 must file claims under the Act. Moreover, even though petitioners with claims based on vaccinations after September 30, 1988 must first file under the Act, they may subsequently reject compensation awarded under the Act and file an action under applicable state tort law. Thus, as long as the specter of significant tort liability remains, CLI cannot risk further reductions in the price of DTP without endangering the steady supply of this vital vaccine.

We hope the Act will provide an increasingly attractive alternative to litigation and result in fewer cases actually entering the tort system. To that end, we are committed to undertake periodic reviews of data generated by the Claims Court in handling petitions filed under the Act, to assess the practical effect of the Act on our liability exposure. If at the end of any such review, it becomes apparent that a significantly increasing number of petitioners are accepting their compensation awards and our liability exposure changes, appropriate price modifications to DTP can be made.

The excise tax itself is another problem. The taxes of $4.56 per dose for DTP and $4.44 per dose for MMR, respectively, have resulted in a significant net cost increase to the government and to state health departments. Since the imposition of this tax clearly imposes a burden on state health departments, we support a supplemental appropriation to assist those states in need of additional funds to purchase the required volumes of these vaccines.

Retroactive Injury Funding Needs

The Omnibus Budget Reconciliation Act of 1987 provides that vaccine-related deaths or injuries based on vaccinations occurring prior to October 1, 1988 are to be compensated from future general revenues. For the fiscal years 1989-1992, $80 million per year has been authorized for these cases. However, funding of the full authorization with which to compensate these families is not guaranteed. CLI strongly urges this Committee to appropriate funds for what are known as "prior" injuries. It would be unfair to exclude these children from compensation merely because these prior injuries occurred before the effective date of the legislation. It was their experience that provided the impetus for the Act; denial of compensation for retroactive claims would violate the spirit of the legislation.

U.S. Claims Court Appropriation

CLI also supports an appropriation for the administration of this Act by the United States Claims Court. At this time, judges of the court and their staff are becoming familiar with the substantive and procedural aspects of processing these petitions. However, without an appropriation to fund the administration of this function, the court will be hampered in its efforts.

Summary

In conclusion, I urge the Committee to appropriate the amounts needed in order to insure the continued success of the immunization program. An untold number of lives have been saved through this ability to prevent diseases. Recently, physicians have been able to add still another life-saving weapon in their armamentorium against disease when the FDA granted a license for Connaught to market ProHIBIT, a breakthrough vaccine against Haemophilus influenzae type b (Hib disease.) ProHIBIT allows nearly twice as many children to be vaccinated than was previously possible against Hib disease, the leading cause of bacterial meningitis in young children. Rep. Henry Waxman, noting that "thousands of infants will be forced to forgoe this important preventive health measure," has called for a supplemental appropriation with which to fund the government's purchase of ProHIBIT. This was not a "first generation" vaccine. It came after 10 years of research and development and has a greater ability than its predecessor to protect. We hope that the a similar situation will evolve with a new pertussis vaccine that will reduce the number and degree of vaccine-related injuries. Connaught has devoted a significant share of its research resources to such an effort.

The immunization programs remain remarkably cost-effective, despite the overall increase in costs to federal and state governments and to the private sector during the past five years. The introduction of vaccines over the last several decades has resulted in tremendous savings for the nation in long-term health care and disability costs. We look forward to a future in which current research efforts will lead to superior vaccines and we renew our commitment to supplying these vital products to maintain the public health.

CONCLUSION OF HEARING

Senator **Bumpers**. You have all been very helpful to us, and I want to thank you most sincerely for your fine statements and for coming to be with us this afternoon.

We will stand in recess subject to the call of the Chair.

[Whereupon, at 4:50 p.m., Tuesday, March 15, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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